National Institutes of Health (U.S.) Office of the Director

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DR. ROBERT S. STONE'S

SPEECHES AND ARTICLES

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SPEECHES AND ARTICLES BY DR. ROBERT S. STONE

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7/11/73	Ft. Detrick, Md.	"Biomedical research and the Nation's health." Presented at the White House Health Seminar.	1
11/4/73 PUBLISHED	Wash., D.C.	"Status and trends of the NIH extramural research support program." Presented to the Council of Academic Societies during the 84th Annual Meeting of the Assoc. of Amer. Med. Colleges. Published in the J. of Med. Education, Vol. 49, July 1974.	2
11/28/73	San Antonio, Texas	"The role of an NIH program on carcinogenesis and cancer prevention." Keynote address presented to the Second Annual Carcinogenesis Collaborative Conference.	3
1/24/74	Brooklyn, N.Y.	"Care and feeding of excellence--the science administrator's raison d' etre." Presented at Brooklyn College of the City University of New York.	4
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OUTLINE
W.T. Carrigan
6/28/73

BIOMEDICAL RESEARCH AND THE NATION'S HEALTH*

Robert S. Stone, M.D.**

I. Grateful for this opportunity to discuss an important linkage that must be clarified and strengthened in the public mind.

   A. I refer to the essential connection between biomedical research and the Nation's health.

      1. Certainly the fact that medical practice draws heavily upon the scientific laboratory is widely appreciated.

      2. But the nature of that connection--the absolute dependence of medical advancement upon biomedical R&D, and the routes by which new knowledge finds its way into the hands of the practitioner--are only dimly understood, I believe, by the general public and many of its leaders.

      3. Thus the real role of the National Institutes of Health and the hundreds of universities, hospitals, and government and private institutions conducting similar research is also vague in many minds.

   B. The linkage is one that science writers might explore in their articles, taking a broader approach than that of the typical news story.

      1. As you all know, medical research findings, even when very important, are seldom dramatic. They may not lend themselves to illustration. They are hard to connect with human values.

      2. This is the challenge.

      3. Science writers have done very well in explaining clinical advances--the occasional breakthrough, spectacular achievements, ethical controversies, etc.

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*White House Health Seminar, Fort Detrick, Maryland, July 11, 1973.

**Director, National Institutes of Health, U.S. Department of Health, Education, and Welfare, Bethesda, Maryland.

4. But this is the endpoint--the tip of the iceberg. The story is seldom a window on the many and complex factors of discovery.

5. The story of medical advancement is one that also involves--at the levels of lab and clinic--astute deduction, organizational problems, ethical considerations, intrigue, personalities, human interest.

6. And there is a very serious purpose in exploring all this: the need to expand perspectives on the world of science, teaching, discovery, development, testing, regulation, administration, legislation--with a view to bringing the public and its representatives more effectively into the formulation of public policy vital to medical progress.

II. Among the policy issues calling for widespread understanding is that of program balance.

A. Legislators and administrators, both lay and scientific--including leaders in the private sector--must constantly decide how research funds and efforts are to be deployed. Long-term adjustments are always in process.

1. Some of the options are basic vs. applied research, undifferentiated vs. targeted support, science vs. service, and the various health problem categories--heart vs. cancer vs. mental health, etc.

2. Some of the factors of policy are the relative magnitude of health problems, availability of funds, past and present investment, research opportunity, state of the art.

3. The decisions belong largely to the Federal budget-making process, for the Federal Government supports nearly two-thirds (63 percent) of the Nation's medical R&D.

4. National leaders (rather than scientists or physicians) ultimately make these important decisions.

5. Science writers play an important part in the educational process that helps leaders make wise judgments.

B. Decisions on public policy in science and medicine involve a complex interaction.

1. The science administrator evaluates and advises.

2. Legislative and executive leaders decide broadly on program emphasis.

3. Program workers perform.

4. The public monitors, influences--and pays the bill.

5. The science writer supplies essential links between the science itself, with its complex subject matter, and the social fabric--government, industry, philanthropy, and the people.

III. Now I'd like to say a few words about two major NIH programs--cancer and heart research.

A. These diseases, as you know, are our leading causes of death, accounting for two-thirds of all deaths in the Nation today.*

B. In the NIH budget for FY 1974, their study accounts for about half of the research and training funds.

C. Trends in the two National Institutes concerned with these problems are toward more research under contracts (vs. grants) and more large grants to program projects and research centers.

D. This implies more central direction in the research itself.

E. The trend is consistent with NIH policy stated as early as July 1967--a policy of identifying opportunities for applied, or "targeted," research and of mounting programs to exploit them. Two examples that come immediately to mind are

1. Virus cancer studies and

2. Drugs and other approaches to hypertension. [Flexible: expand if time permits.]

F. It may be safely predicted that as programs mature in all the Institutes, a shift toward contracts and center grants, with a view to advancing Federal missions to conquor disease, will be the shape of things to come.

G. I believe the plans, programs, and achievements that emerge from this process will provide the grist for articles that attain new levels of sophistication in science reporting.

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*Diseases of the heart, 38 percent of all deaths in 1970 (provisional); malignant neoplasms (all forms), 17 percent; cerebrovascular disease, 11 percent.

Status and Trends of the NIH Extramural Research Support Program

Robert S. Stone, M.D.

Abstract—The federal health establishment is continually searching for more effective ways to support biomedical research as well as to maintain the strength and viability of the nation's academic institutions. The National Institutes of Health in particular is devoting considerable attention to improving its mechanisms of research support. Its administrators and staff are currently engaged in implementing the recommendations of a special NIH committee which looked into this matter. They are, for example, seeking to improve communications with the academic community, to utilize the NIH advisory apparatus more effectively in the development and implementation of NIH programs, to develop uniform policies and procedures with specific criteria for selecting grants or contracts to fund extramural research, and to adopt and implement policies for measuring and evaluating NIH grant management practices.

The present condition of and the prognosis for biomedical research support are matters of great interest to the academic community.

The academic health center must have an adequate research program that preserves and fosters an essential balance with teaching and service. But because of the difficulties of financing teaching and service activities, there is sparce support for research from nonfederal sources. Deans, department chairmen, and other administrators know well that the mature medical centers (of whatever size) have become heavily dependent on federal—mostly the National Institutes of Health*—research awards to the degree that their autonomy in choosing the most appropriate subjects and modes of research activity, from their point of view, is often uncomfortably limited. The immature institutions find it difficult to attain a critical mass in particular research fields.

Of course, the rationale for the federal support of biomedical research is not primarily the strengthening and balancing of medical institutions, laudable as this might seem to many who are directly

This article is based on a speech presented to the Council of Academic Societies during the 84th Annual Meeting of the Association of American Medical Colleges, Washington, D. C., November 4, 1973.

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* Member institutes: National Institute of General Medical Sciences; National Institute of Allergy and Infectious Diseases; National Institute of Arthritis, Metabolic and Digestive Diseases; National Institute of Child Health and Human Development; National Institute of Dental Research; National Institute of Environmental Health Sciences; National Institute of Neurologic Diseases and Stroke; National Cancer Institute; and National Heart and Lung Institute.

affected. The first-order federal imperative is the solving of problems of human disease: prevention or diagnosis, therapy, and rehabilitation. As a consequence, the federal health research establishment must search continuously for more effective and efficient ways to use the funds available for these purposes. The critical internal balance issues relate mostly to allocation of resources between short- and long-term goals within the total available for biomedical research. External balance issues relate to allocation of resources within all federally supported science research and development or within science totally.

In recent years efforts to find improved strategies for attacking health problems have resulted in the application of more of the available funds to structured research programs that approach complex problems in coordinated, planned, organized, usually multidisciplinary ways. NIH has called these broad support programs "centers," "program projects," "resources," and "institutes." These organizational units have the common characteristic of the commitment of a significant portion of the grantee institution's program interest and its resources in terms of skilled scientific, technical, and management staff and of physical space and equipment. In the process the relative priorities and opportunities for progress toward self-chosen goals of individual faculty members, as well as the relationships between members of the faculty and the administration, might well be deliberately or inadvertently influenced to a considerable degree. Thus, the program management decisions manifest from NIH are likely to have profound effects on the internal affairs of medical centers as well as on their public stature and image.

Types of Support

It has been the predictable judgment of NIH leaders that progress toward the prevention, amelioration, or cure of diseases of man requires a judicious combination of programs in various fields of investigation and through several mechanisms of support. The individual research project grant, termed "regular" or "traditional," has been the mainstay of NIH extramural research activities since its origin in the National Cancer Institute in 1937. It is still primary; and the current intent is that this mode of encouraging and supporting the individual researcher, whose original ideas and plans are approved by his peers, will continue to be the major support mechanism.

At the same time many who have influenced the pluralistic decision-making process have asserted that some kinds of pressing problems of biomedical research and human health are ripe for a structured attack. The program-project and center grants, collaborative programs, and research contracts offer promise of orderly progress toward agreed-upon goals. Making wise choices along this spectrum of increasingly focused program mechanisms is the responsibility of all who participate in the entire decision-making and resource-allocating process, including NIH program management and the researchers and administrators within the grantee community. This responsibility is assumed with the guidance of the advisory councils and other experienced and dedicated advisory groups. But certainly this has not been a closed system, and influences from larger systems have at times intruded or dominated.

The evolving NIH patterns of research support present a variety of opportunities as well as problems to institutions and to NIH itself. The highest order of concern

must be that funds flow toward good ideas and capable researchers wherever they can be found. These ideas and researchers, however, must be evaluated in the light of the entire NIH mission.

The NIH must make it possible for the little known investigator and the developing institution to receive support. Yet it must also continue to look to the established institutions, with their larger faculties of experienced researchers, to undertake assaults on many of the multifactorial, heretofore intractable problems. As a consequence of the latter policy, it appears from some viewpoints that the good get better and the lesser established are undersupported.

Program Growth

NIH data illuminate the past effects of the growth of broad programs on grantee institutions. The accompanying figures illustrate some of these relationships over time and may help provide a common, more encompassing perspective.

Figure 1 shows the dollar amounts obligated for NIH extramural research programs in actual and in constant dollars for fiscal years 1967 to 1974 (estimated). Although the actual dollars increased by more than 60 percent, it is evident that the real increase in buying power, as measured by applying the gross national product deflators, was only a third as much, or about 20 percent.

It is also apparent that the expansion achieved was in the areas of research and development contracts and of program-project and center grants. This is especially observable when examined in terms of constant dollars, in which the level of support for regular research grants shows a decline.

These differential effects are seen from

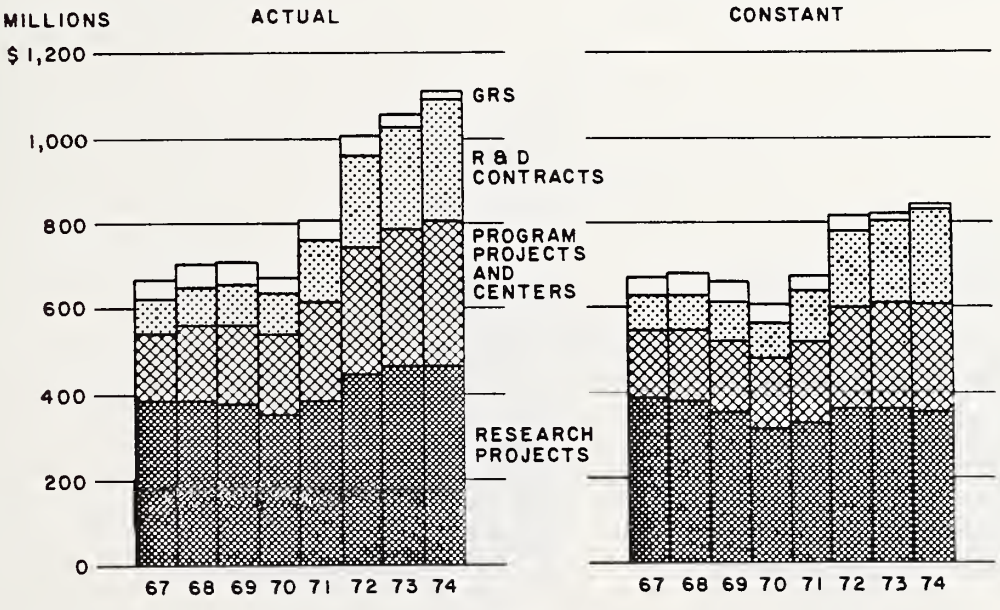


FIGURE 1

NIH extramural research program awards in actual and constant dollars, fiscal years 1967–1974. These are estimated figures which reflect fiscal 1974 President's budget, excluding $227.6 million released in fiscal 1974 from fiscal 1973 reserve. (GRS = general research support.)

Figure 2 to have been primarily related during the past four years to the awards made by three of the institutes: cancer, heart and lung, and child health and human development. The steep increases, especially in terms of research and development contracts and of program-project and center grants, account for virtually all of the NIH increases during this period. In fact, during the past three years, the extramural research programs of the rest of the institutes and research divisions have declined by 10 percent.

These effects are further delineated in Figure 3, which shows the percentage distribution of the same data by grouped institutes. On the left the obligations for the cancer, heart, and child health institutes show the increasing proportions of research and development contracts and program-project and center grants accompanied by simultaneous decreases in regular research grants.

For the group of seven institutes whose overall program support has not increased (arthritis, allergy, dental research, neurology, general medical sciences, eye, and environmental health sciences), the proportion of traditional research grants has remained constant at a much higher level, and research and development contracts have received a considerably smaller proportion of available funds than is the case for cancer, heart, and child health.

Figure 4 illustrates the awards of the cancer, heart, and child health institutes individually, by type of support, for fiscal years 1967 and 1974 (estimated). The aggregate increases for each of these institutes are striking. Even more so are the proportionate decreases in regular research grants and increases in research and development contracts and program-project and center grants for each institute.

Figure 5 shows the differing extent to

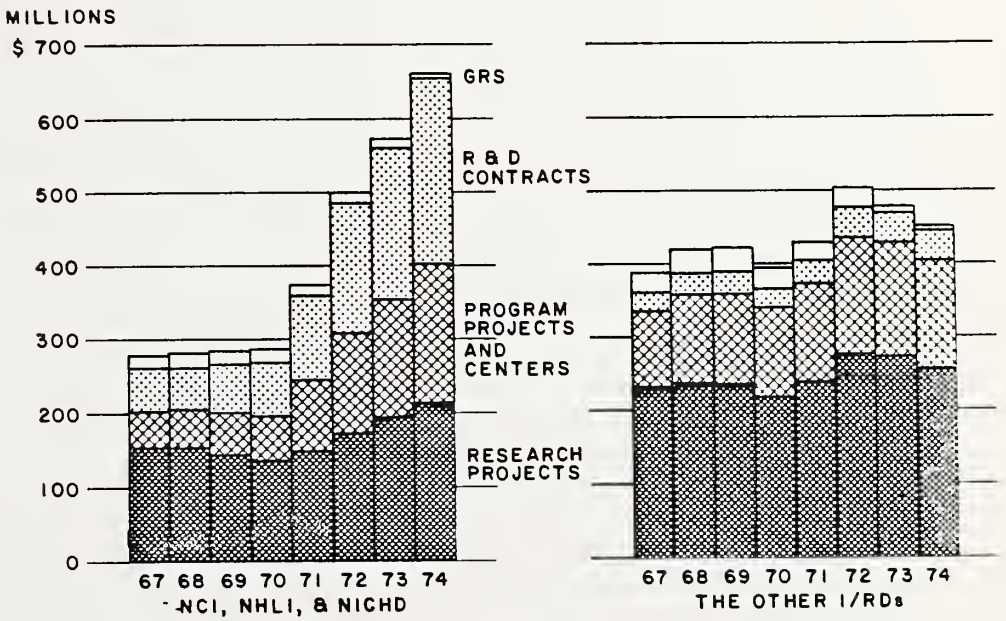


FIGURE 2

NIH extramural research program awards by grouped institutes, fiscal years 1967–1974 (estimated). (I/RDs = institutes and research divisions.)

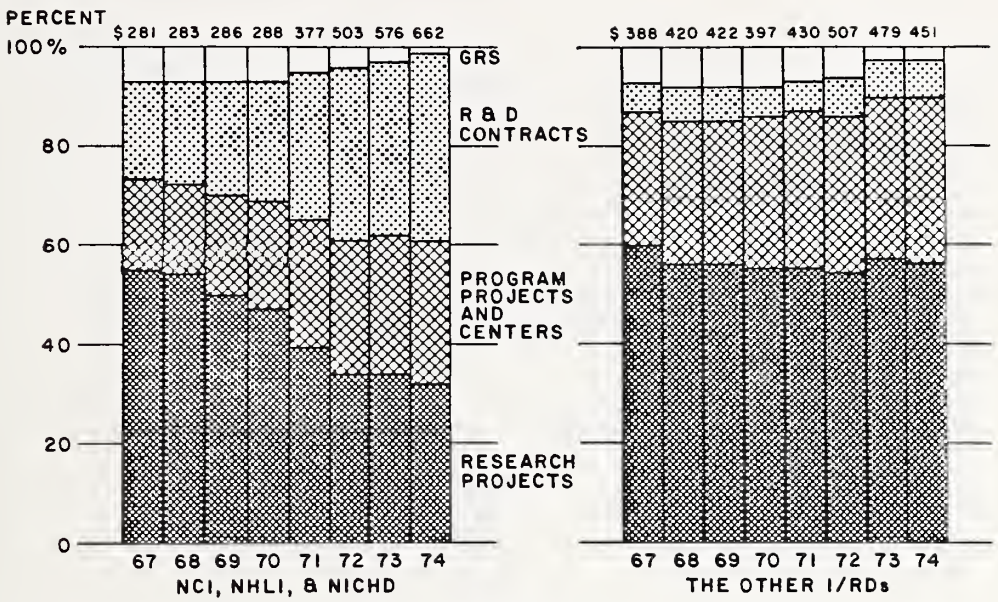


FIGURE 3

Percentage distribution of NIH extramural research program awards by grouped institutes, fiscal years 1967–1974 (estimated).

which the 10 NIH institutes use regular research project grants as compared with the large grant mechanisms, that is, program-projects or program-projects plus centers. The graph presents the ratios among these mechanisms. The allergy, arthritis, and eye institutes, as compared with the others, have maintained a severalfold higher ratio of regular project grants to large grants.

Figure 6 presents a picture of the diversity among 10 representative grantee institutions (number-coded along the x-axis) in terms of their receipt of the three principal types of NIH grants. These 10 grantees are among the 30 which currently receive the most NIH research grant support (between $7 million and $21 million). Nine of these include a medical school as the chief or sole component. Although eight of the 10 receive larger amounts of regular project grants than of program-project or center grants, the variation among them is considerable—up to 30-fold in one case.

Similar diversity among 10 mid-size medical school grantees is shown in Figure 7. Total NIH research grant support in these schools ranges from about $4 million to $7 million. The bulk of the support in each case is in traditional project grant form; but the acceptance and use of program-project and center grants, while nearly negligible in some, is substantial in others.

These data would be of even greater interest if presented in terms of medical centers rather than medical schools or universities. Interest in the medical centers has grown with the increasing awareness of the essential interlocked relationships among medical education, postdoctoral training, and health care services. Unfortunately, a generally accepted definition of organizational or even fiscal boundaries of these centers has not yet been achieved by

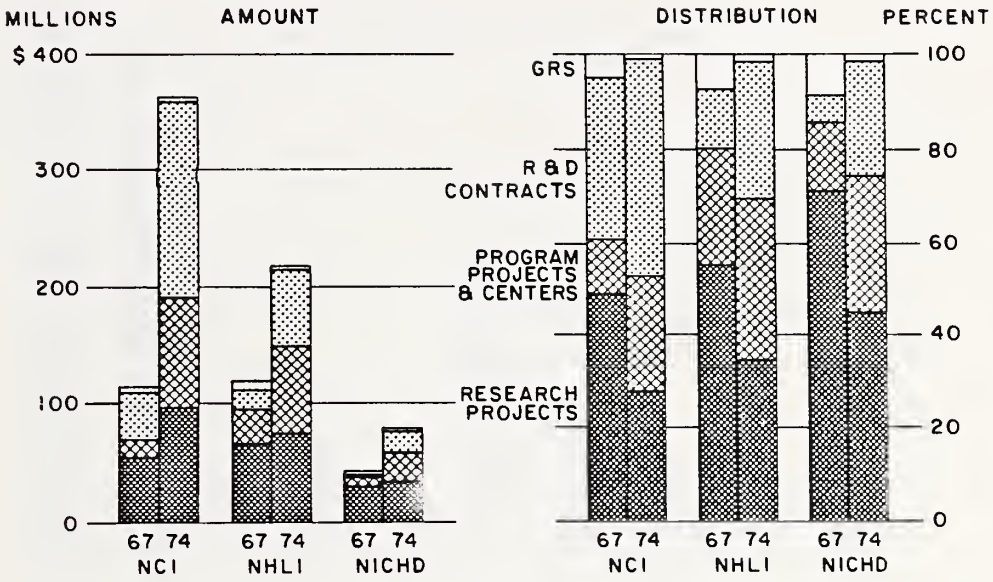


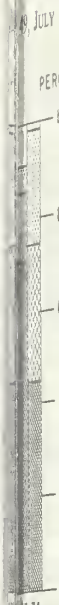
FIGURE 4
Extramural research program awards for three NIH institutes, fiscal years 1967 and 1974 (estimated).

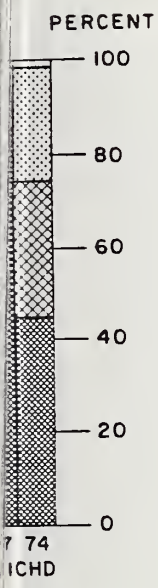
the NIH, the Association of American Medical Colleges, or other interested bodies. The difficulty lies in the diversity of the medical centers. They vary widely in organizational structure, in relationships with affiliated hospitals, and in degree of autonomy within the parent academic institution. The relationships between the medical schools and their teaching hospitals are especially diverse, with school-hospital groups ranging from essentially single organizations through legally separate but closely affiliated dean's committee hospitals through independent hospitals offering cooperative opportunities for research and training to hospitals maintaining research and training relationships with two or more medical schools.

The data in the figures were collected by the staff of the NIH Division of Research Grants from files on individual awards for all kinds of research grants made by the NIH institutes and the Division of Research Resources. Because of the limitations of the data, identified institutions are not fully equivalent or comparable in some cases. The essential research and intellectual unity of some medical-school–hospital complexes that were necessarily treated in the NIH data collection system as separate grantee entities is acknowledged. Data analysts are engaged in refining the characterization of the actual medical research communities with which NIH deals.

Evaluation

The reasons for such great institutional variability are not clear to NIH program officers. In fact, these data are sufficiently puzzling and challenging that NIH has set up a Center Grants Task Force composed of the staffs of the scientific program and the grants management groups to study these matters and to learn about opinions and effects among grantee institutions. The intent is to understand





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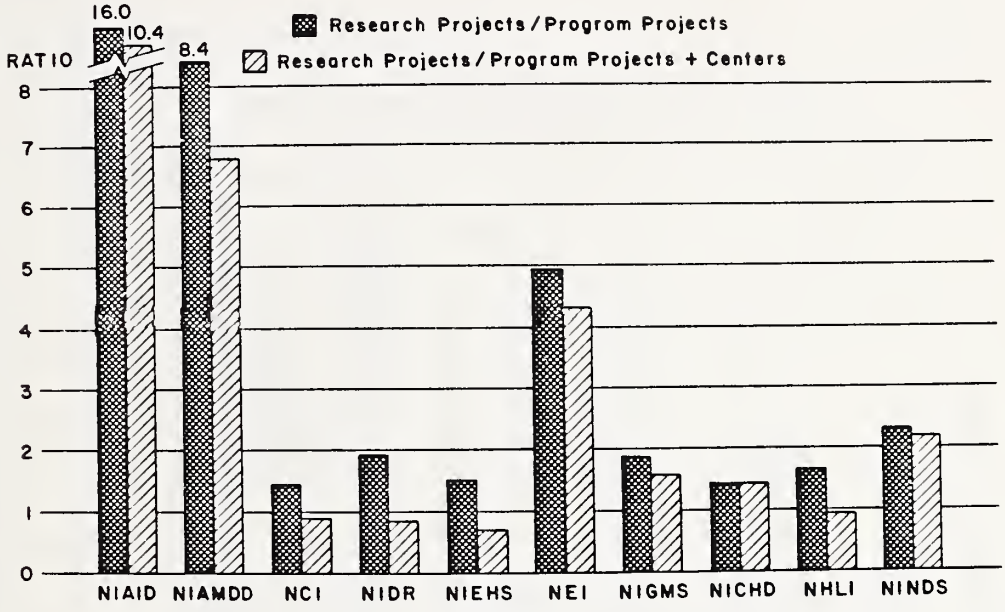


FIGURE 5
Institutes' use of research grant mechanisms, ratios of amounts awarded, fiscal year 1973.

3. Because of identified inalent or com- essential reuity of some mplexes that the NIH data arate grantee Data analysts characterizaresearch comeals.

t institutional NIH program are sufficiently that NIH has sk Force com- scientific progement groups to learn about g grantee instio understand

through study of NIH awards data and the practices of the institutes, and especially through discussions with grantee scientists and administrative persons, how these different grant mechanisms affect institutions. Hopefully, this should provide answers to the question of how NIH research support mechanisms are perceived by grantee personnel with different responsibilities and, therefore, different viewpoints; why some grantees apparently view these mechanisms differently from others; and what these program mechanisms do to as well as for the NIH grantee community at different system levels.

Even while the NIH is wrestling with these complex decisions regarding balances among its programs, it is also engaging in a series of important and challenging exercises concerning the means to implement those programs and to learn how to deal more effectively with the external research communities. In December 1972 a number of suggestions from both inside and outside NIH led then NIH Director Robert Marston to appoint a committee of senior NIH staff members to take a careful look at the development and administration of NIH programs.

The committee was asked to examine particularly the processes for selection and implementation of these programs and the projects within them. This Program Mechanisms Committee was most effectively chaired by Dr. Theodore Cooper, director of the National Heart and Lung Institute. The members focused attention on some of the issues mentioned earlier as they had been reviewed and analyzed in previous reports as well as in their present contexts. The committee discussed these ideas within its own circle and called on other sources for suggestions, including members of NIH and the academic and industrial communities.

The deliberations of the Program Mechanisms Committee came to fruition

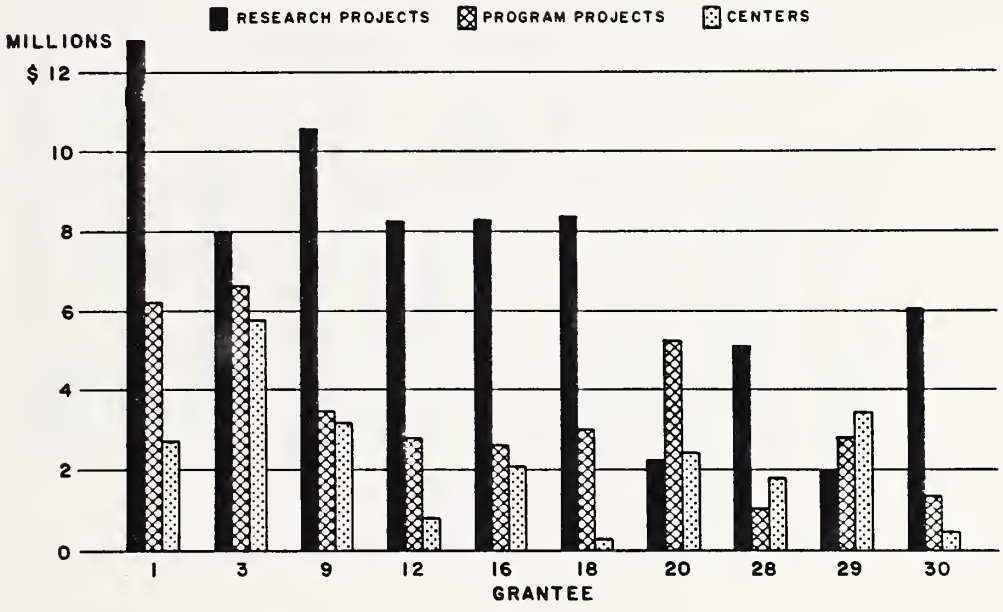


FIGURE 6
Relative NIH support among 10 large grantee institutions, fiscal year 1973.

in February 1973 in the form of a report, which included seven recommendations aimed toward the resolution of certain problems. The resolutions are currently under intensive study by staff, with a view to the development of those that seem favorable into useful NIH policies or procedures. Some of the proposals impinge significantly on NIH relations with the research communities outside NIH.

Improving Communications

Recommendation 6 of the committee report relates directly to academic institutions. This recommendation suggests primarily that NIH should take steps to improve communications regarding mechanisms for initiation, implementation, and evaluation of NIH programs with its internal staff, advisory councils, and committees; with those in other levels of government; and with the outside scientific communities and the public.

It is essential in this turbulent world to improve the dialogue among different types and levels of NIH officials regarding their roles and responsibilities in the administration of their programs. NIH itself is anything but monolithic. Even more important, however, are the various comments and criticisms received at NIH regarding the way it does business with extramural researchers and organizations. There is unquestionably a real need to improve communications with the outside world.

There are, of course, many individuals in the extramural communities who are thoroughly familiar with most of the NIH operating policies and procedures and the mechanisms for interacting with grantee and contractor institutions. But even some of the most knowledgeable, as well as the bulk of research investigators and administrators, have misconceptions or at least significant gaps in their awareness of how the NIH conducts its busi-

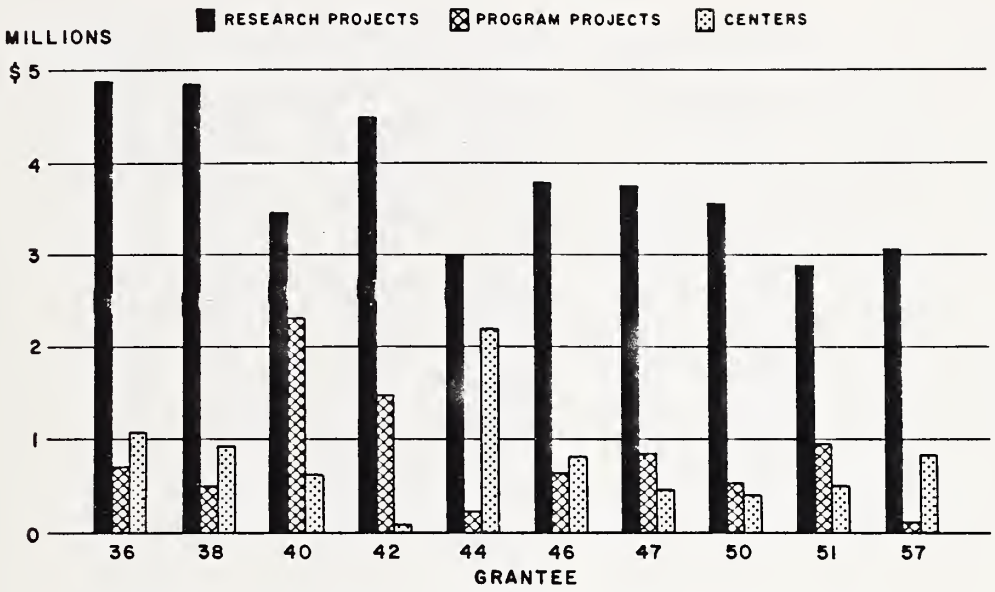


FIGURE 7
Relative NIH support among 10 mid-size medical schools, fiscal year 1973.

ness. It seemed to the committee that this deficiency demands vigorous steps to improve communications with the outside communities.

The committee recognized additionally that adequate communications mean more than simple exchanges of information. They realized that much more must be done at NIH to improve the actual processes by which programs are selected and priorities are established. In this regard recommendation 1 urges a more effective utilization of the NIH advisory apparatus in the development and implementation of programs.

Many medical educators and administrators are familiar with the roles that NIH advisory councils and technical review committees have played over the years in the review and evaluation of grant applications and contract proposals. Less well recognized, but equally vital to the synthesis and development of NIH programs, has been the contribution of these advisory groups to mission-setting, that is, to the selection of program goals and mechanisms intended to be responsive both to solving manifest health needs of the country and to supporting high-quality science and manpower development.

It is important to remember, for example, that many of the instruments of support, as well as the specific programs for which they have been used, originated from deliberations and recommendations within some of the NIH national advisory councils. Similarly, many of the technical initial review committees concerned with grant and contract activities have been responsible for suggesting significant new directions or targets for the course of biomedical research. These have been expressed in new program thrusts by the various institutes. Thus, a reciprocal relationship has developed. The advisory group members contribute significantly to the decision processes for selec-

tion of NIH goals and the setting of priorities. Then NIH staff, reporting back to advisory groups on progress in these program areas, provides feedback, enhancing the consultants' awareness of the broad picture and, in turn, enabling them to make more effective recommendations.

Many such deliberations, it should be pointed out, have taken place in closed meetings. This has lent an air of mystery to the proceedings and has perhaps even aroused suspicion as to their impartiality. Consistent with recent developments mandated under the Freedom of Information Act, the NIH Program Mechanisms Committee recommends that such discussions be opened to the public. Moreover, it advocates that the advisory groups assist in the selection of programs most responsive to public needs. Such steps will give considerably greater visibility to the program development process at NIH. They will also help to improve the systems by which NIH institutes establish and modify their objectives, priorities, resource allocations, and program management. All the NIH institutes are developing their advisory committee agendas to include in open portions of the meetings discussion of many broader policy elements relating to their changing programs.

Administering Support

Even with these approaches toward what it is hoped will be improved procedures for program development at NIH, there is yet another and still more formidable hurdle ahead. The current systems for receiving, reviewing, awarding, and managing NIH grants have evolved, through many years of trial and experience, to the point where they are now fairly well standardized throughout the institutes. Policies and procedures governing granting activities have been codified and published in a number of documents for both internal and external use. They are thus familiar and understood throughout the biomedical community, though it is recognized that they must be subjected to continuing examination and revision.

NIH contracting activities, however, present a picture considerably less clear. The use of contracts for research and development has grown most rapidly at NIH in only the past six or eight years. Because research and development contracts derive from procurement activities, the policies and procedures have tended until now to reflect the various perceived needs and preferences of the institutes rather than to fall into a consolidated and uniform approach such as has occurred through the more centralized grant mechanism. So it was that the Program Mechanisms Committee perceived concern on the part of the performer communities about the diversity of NIH contracting operations. Its recommendation 2 suggests the need for NIH to "establish and refine the use of uniform policies and standard procedures by which its components define, develop, and implement programs, and initiate, review, select, and manage projects funded by contracts, grants, and other awards."

As in recommendation 1, this proposal starts with the selection and development of programs. The report again urges more consistent use of the NIH advisory apparatus at this stage of the process. It emphasizes the need for scientific and administrative analysis as the basis for all grant and contract awards, mentioning technical merit review by qualified peer groups as the key to objective evaluation.

Staffs of the NIH director and the institutes are devoting much time these days to consideration of this particular recommendation, its implications, and steps

toward its implementation. This is hardly a simple task. On the one hand, there is a belief that greater uniformity will help grantees and contractors to understand how NIH does business with them and will thus simplify and perhaps economize the administration of extramural operations. On the other hand, there is a strong aversion to introducing "consistency for its own sake." Furthermore, the different NIH units are understandably reluctant to depart from their own time-honored and cherished ways of doing business. Clearly, effective changes will come about only after thorough examination of present and proposed methods of operation, discussions of the advantages and disadvantages of each, and resolution of problems that might stand in the way of standardizing procedures.

Two additional recommendations are addressed to specific aspects of the implementation of NIH programs. The first of these, recommendation 3, states that NIH should "adopt and implement uniform policies and procedures with specific criteria for selecting the grant or contract method for funding extramural activities." The need for this statement derives from circumstances at NIH which have led to questions regarding the appropriate uses of grants or contracts as award instruments.

The complaint is heard from time to time that more constraints attend the awarding of grants than of contracts and contrarily that some contracts are too flexible and lack the appropriate measures of specifications and conditions. While there have been guideline issuances concerning these two award instruments, currently under development are more specific statements for distinguishing their use in NIH programs. The primary distinction to be drawn is in the location of responsibility for defining and controlling the project; that is, when the performer institution or investigator holds this responsibility, the instrument of choice is the grant; but, when such responsibility resides with NIH, the contract is the appropriate instrument. Further details to implement this recommendation are being worked out within NIH.

Recommendation 4 relates to the need for NIH to "adopt and implement procedures for continuous evaluation of its management practices and develop criteria and techniques to measure performance of operating programs." This recommendation is particularly significant. While NIH programs in the preceding two decades have succeeded admirably, with much of the impetus for program development coming from the outside community, the thrust of present-day responsibilities requires that NIH should consciously and deliberately choose program directions responsive to public needs and priorities monitored by stringent scientific criteria and should maintain a balanced leaven of scientific opportunity.

Good program management requires that NIH be fully accountable to the public for the expenditure of public funds. A true accountability requires that methods be developed and improved by which program performance is evaluated and also by which successes or failures in attempts to achieve specific program goals are measured. One must confess a measure of dubiety about chances for achieving complete success in these directions. There are many variables and uncertainties inherent in trying to measure and evaluate, much less to quantitate, accomplishments in scientific areas. This is particularly so in biomedical research. Nonetheless, the mere introduction of the issues will do much to elevate the aware-

ness of program leaders to the need for giving careful attention to their objectives and for utilizing the best possible tools available to achieve them.

The other two recommendations offered in the Program Mechanisms Report deal with matters primarily affecting administrative operations—how business is conducted within the NIH family and how the agency relates to higher levels of government. One deals with the processes by which transfer funds are transferred between program categories in NIH budgets. The other concerns the organization of the office of the NIH director to deal with the administration of policies and procedures concerning NIH grants and contracts. Both of these are being studied assiduously, but it is yet too early to assess their impact on extramural performers.

However, any changes that are made with regard to these two considerations will reflect the continuing desire to maintain and enhance the long-standing cooperative relationships between NIH and the scientific communities. The steps that are eventually taken, both in choosing the directions for NIH programs and in implementing them through improved policies and procedures, will be designed to continue to serve both NIH and the performer communities in achieving program goals. Such steps will surely further mutual endeavors to solve problems concerning the health of the people of thi country.

Dr. Stone
11/12/73

DRAFT

PRESENTATION ENTITLED

"THE ROLE OF AN NIH PROGRAM ON CARCINOGENESIS AND CANCER PREVENTION"

Robert S. Stone, M.D.
Director
National Institutes of Health

KEYNOTE ADDRESS
SECOND ANNUAL CARCINOGENESIS COLLABORATIVE CONFERENCE
San Antonio, Texas
November 28, 1973

Sponsored by the
Carcinogenesis Program
Division of Cancer Cause & Prevention
National Cancer Institute

1. Laffeatte /NCI
2. Mr. Whaley - 11/12/73

Because of its involvement in the identification, evaluation, and prevention of environmental cancer hazards, the Carcinogenesis Program at NCI is at the center of a wide spectrum of interests: they range from scientific to disease-prevention interests, and from economic and regulatory interests to consumer and environmental protection concerns.

The emergency of environmentally caused diseases as a major component of modern medicine has received considerable attention in several federal agencies, including NIH. A Division of Environmental Health Sciences was established in 1966 and became a full NIH Institute in 1969.

Several Institutes have devoted portions of their program to the study of environmental causes of diseases and their prevention. A major example is given by this Carcinogenesis Program of the NCI.

Its rapid growth is an indication of the importance of environmental cancer in today's society.

SLIDE 1

Present knowledge already indicates that a majority of the cancer deaths in the United States is attributable to environmental factors. For many forms of cancer, etiologic factors have not yet been clearly identified, and they may well contribute to the pool of environmentally caused cancers. A large group of cancers is related to endocrine

factors, which are not environmental *per se*, although they can be influenced by exogenous factors, including the intake of hormonal preparations.

SLIDE 2

The identification of carcinogenic factors and the prevention of their effects requires a complex multidisciplinary approach.

Documentation is needed on the environmental distribution of carcinogens and on the extent of exposure of people in different circumstances. Since we cannot test the effect of carcinogens on man, and since epidemiological studies on carcinogen exposure are very difficult and very lengthy, we need to rely on animal bioassays to detect carcinogens. In turn, the limited sensitivity of currently used bioassay methods, based on relatively small number of animals, indicates the need to develop new and possibly more selective and sensitive bioassay models. The progress made with *in vitro* systems of transformation by chemicals is very encouraging, and may be expected to lead also to the development of methods for direct transformation of human cells *in vitro*.

These and many other advances in experimental pathology give us the necessary tools to study the pathogenesis of the major types of cancer in the context of their organs and tissues of origin, with their special regulatory mechanisms and their characteristics of cell differentiation.

Through such an analysis of the pathogenesis of the various types of cancers, we are learning to identify the regulatory mechanisms which

control not only the metabolic activation of carcinogens and their interaction with target cell constituents, but also those host factors which control the growth of transformed cells into an invasive tumor, particularly at the immunological level.

Epidemiological approaches can help us to verify in the population the correlations of etiologic factors and pathogenetic mechanisms with the actual appearance of cancer in man.

SLIDE 3

As our knowledge of cancer causation extends, so does our potential for its prevention. Prevention can take two main approaches: on one hand, the removal of carcinogenic agents from the environment of man, or the reduction of exposure to the minimum possible extent; on the other hand, we can develop methods for inhibiting the carcinogenic process in the host through pharmacologic or immunologic approaches.

The control of the host response requires much further research effort, both at the basic and at the applied level.

The prevention of cancer through reduction or elimination of environmental exposures requires in most cases the interplay of different groups in our society.

SLIDE 4

The Government participates with all its three branches in the control of environmental carcinogens, Congress provides the legislative basis through laws directed at specific sectors of the environment, such as food additives, drugs, or pesticides. These laws establish

the basis for specific regulations issued by Departments or Agencies of the Executive Branch, such as the FDA, the EPA, and USDA, the OSHA in the Department of Labor, etc. Many of these agencies also participate in the enforcement procedures together with the Judiciary Branch. As you well know, the Executive Branch fulfills also another very important function in this context, as directed by law: and this is the conduct and support of research, which provides a great deal of the basic knowledge on which legislative and regulatory criteria are derived; it also provides a large amount of bioassay work. The private sector of our society is obviously involved in several different roles in the field of environmental cancer. Industrial and agricultural technologies are the major contributors in the production of most known environmental carcinogens. Industry also supports research and bioassay programs. The general population can be regarded as the target of exposure, although certain groups in it can be identified as specifically exposed to certain consumer products or to occupational exposures.

A key role is played by the scientific community, particularly through its academic institutions, in providing the backbone of expertise, research, and knowledge which is the basis for evaluation of carcinogenic hazards and of the means to prevent them in our society. In this role the scientific community includes scientists in Government agencies, particularly NIH, and is also aided by the role of private foundations and health agencies, such as the American Cancer Society.

Finally the news media have an important role in the dissemination of scientific information through the technical literature and also through the general press which contributes to the formation of a

public opinion on the causes of cancer and on the options for its prevention. Needless to say, there is a feedback from each of these segments of society into the others.

A particular problem concerns the relation of research to regulatory functions in Government agencies.

The process of regulation for exposures to carcinogens is based on a review of chemical, toxicological, and biological data, with specific reference to the understanding of the mechanisms of cancer induction.

Therefore, there is a close interplay between regulatory criteria and scientific knowledge about the biological effects of a chemical or group of chemicals.

Over the last several years, NIH has become progressively more involved in a collaboration with regulatory agencies, such as FDA and EPA. The Assistant Secretary for Health has established a Committee to Coordinate Toxicology and Related Programs which includes several NIH representatives and provides broad liaison of the federal agencies.

SLIDE 5

An Interagency Collaborative Group on Environmental Carcinogenesis was set up by the Carcinogenesis Program at NCI to maintain close liaison with other federal departments and agencies at the working level. The exchange is beneficial in both directions. Much useful information on environmental exposure problems and on needs for bioassays of environmental chemicals is obtained by the specialized

programs of different agencies concerned with product categories or environmental sectors. We at NIH, on the other hand, can contribute much useful information and generate new research on specific effects of chemical carcinogens, on their mode of action, on their metabolic fate, on the validity of animal models and on human cancer epidemiology.

In addition, while many other agencies consider individual segments of the environment or individual products for regulation, we at NIH can take a look at the overall disease problem created by the simultaneous multiple exposures to mixed agents that characterize the environment of man.

We are asked, more and more often, to participate with our expertise in the evaluation of chemicals under regulatory consideration. This is a point that needs a balanced view of our role. NIH is not a regulatory agency and should in no way assume that role. However, we are asked to give our cooperation of expertise and documentation to regulatory agencies and we do so as fully as it is possible with our limited resources. Our role is that of a disease-oriented and research-oriented agency, and our contribution is best addressed to the scientific understanding that forms the rational basis for regulatory activities. Our mandate is, also, that of developing the most effective attack against major diseases and to that effect there is legislation, such as the National Cancer Act of 1971, which provides for a coordination of effort through all federal programs towards the control of disease. We have a task, therefore, to represent to the legislative and regulatory arms of Government the most effective options for the control of cancer.

SLIDE 6

Our role in carcinogenesis and prevention is that of defining the following steps:

Environmental exposure;

Epidemiologic pathology;

Chemical identity and detection;

Carcinogen metabolism and activation;

Bioassay methods and their development, design, and evaluation;

Tumor pathology, particularly in comparative terms, relating experimental animals to man; and

Tumor pathogenesis in morphological, biochemical, and immunological terms.

On this basis, it is our duty also to establish what is, at the present state of our knowledge, the scientific basis for evaluation of criteria for the identification and elimination of carcinogenic hazards and their impact on human disease.

In these matters, ours is the role of science, that of objective evaluation of facts in the pursuit of the understanding of the causes of disease. Our role is also that of relating our scientific approach to the prevention and control of one of the most devastating diseases: and this requires that the scientist extend his consideration to the public health implications of his research.

The more rigorous our science, the more valid will be our advice for public health action.

ENVIRONMENTAL EXPOSURE	IDENTIFICATION OF CARCINOGENS	PATHOGENESIS OF CANCERS	HUMAN CANCER OCCURRENCE

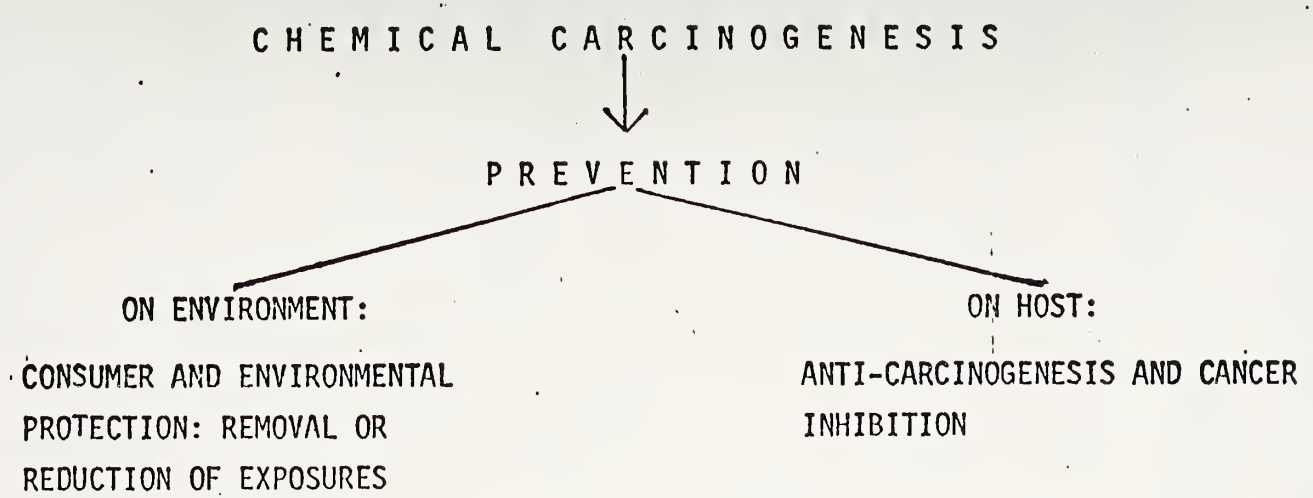
RESEARCH AREAS

ACTIVITIES

CHEMICAL AND ENVIRONMENTAL ANALYSES	BIOASSAYS	BIOLOGICAL MODELS (ORGAN, TYPES)	HOST CONTROL: BIOCHEMICAL, IMMUNOLOGICAL	EPIDEMIOLOGY

(CARCINOGENESIS PROGRAM) (FIELD STUDIES)

Table 2


CHEMICAL CARCINOGENESIS
PREVENTION
ON ENVIRONMENT:
CONSUMER AND ENVIRONMENTAL PROTECTION: REMOVAL OR REDUCTION OF EXPOSURES
ON HOST:
ANTI-CARCINOGENESIS AND CANCER INHIBITION

Slide 3

CARCINOGENESIS PROGRAM, NCI
INTERAGENCY COLLABORATION

AGENCIES

Non-Regulatory Mission

DOD (Environmental)
(Occupational)

DOC/NOAA (Atmospheric and Oceanic)

USDI (Fish and Wildlife)
Aquatic Environment

NSF (Environmental)

NASA (Environmental)
(Occupational)

Smithsonian Institution
Aquatic Environment

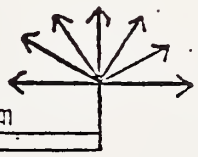
DHEW/CDC-NIOSH (Occupational)

DHEW/NIH-NIEHS (Environmental)

DHEW/NIH-NLM (Toxicon)

DHEW/NIH-NCI

1. Cancer Control
2. Division of Cancer Cause and Prevention
   - a. Field Studies and Statistics
   - b. Carcinogenesis Program



Regulatory Mission

DHEW/FDA (Environmental)
Bureau of Foods (Foods)
Bureau of Drugs (Drugs)
NCTR (Environmental Toxicology)

EPA (Environmental)
Air and Water Programs
Pesticide Program
Toxic Substances
Radiation Standards

Consumer Product Safety Commission
Consumer Products

DOL/OSHA (Occupational)
Occupational Health

AEC (Environmental)
Air and Water Effluents
Radiation Controls

USDA (Environmental
Agricultural Products

DOT (Environmental)
(Occupational)
Transshipment of Hazardous Materials

ENVIRONMENTAL EXPOSURE

EPIDEMIOLOGIC PATHOLOGY

CHEMICAL IDENTITY AND DETECTION

CARCINOGEN METABOLISM AND ACTIVATION

BIOASSAY METHODS: DEVELOPMENT, DESIGN, EVALUATION

TUMOR PATHOLOGY

TUMOR PATHOGENESIS

EVALUATION CRITERIA: IMPACT ON DISEASE

Table 6

TAB 4

#7 8

CARE AND FEEDING OF EXCELLENCE-- THE SCIENCE ADMINISTRATOR'S RAISON D'ETRE*

Robert S. Stone, M.D.**

It is highly gratifying to participate in the dedication of this magnificent science complex at Brooklyn College--a place that certainly evokes poignant memories for me. I am truly delighted to join in your salute to chemistry's past accomplishments and its future promise. The record of constant advancement of that field, as well as the continued outpouring of its benefits to mankind, epitomize excellence and service in science. This superb science complex, in the years ahead, will surely contribute abundantly to that great tradition.

To my mind, it is entirely fitting that administrators of contemporary science programs should be preoccupied today with the matter of excellence. The title of John Gardner's thoughtful book--*Excellence: Can We Be Equal and Excellent Too?*--in focusing on a crucial question, goes far toward explaining the deep interest of everyone concerned with social purpose and relevance. For the science administrator, there are additional serious considerations--for example, the effect of abrupt changes in funding, whether up or down, on the quality of research. Today I will try to touch upon a selected few of the science administrator's problems and considerations, as I have encountered them in a particular setting, in the pursuit of excellence in the scientific enterprise.

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*Presented at Brooklyn College of the City University of New York, Brooklyn, N.Y., 1/24/74.

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The Tradition of Excellence in Science

The quality of American science in general reflects a system and set of standards that transcend the performing institutions. The scientific societies and their open refereed journals, mostly oriented toward disciplines--chemistry, biology, astronomy, physics--are responsive to the ideals of science itself. It is essentially a truism that shoddy science is little better, and often worse, than no science at all. Conversely, and fortunately, a tradition of skepticism, precision, criticism, and of gradual building upon verified facts results in excellent science wherever those standards are preeminent.

The central problem and indeed obligation of the science administrator today is to create a local environment in which the prevailing high standards of scientific investigation can be dominant. It is essential to recognize and agree that the system embodied in the Western tradition of scientific disciplines, with its built-in mechanisms for verification and peer review to check unproductive research, is a highly effective cybernetic system for quality control. The administrator must seek to foster this tradition and permit it to flourish.

In most institutions which award grants or contracts for research or which directly employ scientists, the operational path to excellence is found through selection, management and evaluation:

- Selection of the best available human talent.
- Selection of projects affording high potential for advancing knowledge relevant to given missions.
- Management of the facilities and resources in and through which scientists and their support groups can perform efficiently.

- Management of educational institutions.
- Evaluation of proposals, operations and results.

National Need and Federal Support of Science

In citing examples from institutions, I will draw heavily upon Federal ones, and particularly the National Institutes of Health. This is not to say, of course, that I view the care and feeding of excellence as an occupation unique to the Federal science establishment. Academic, industrial and philanthropic institutions share many of the same problems and have adopted similar approaches. However, the great magnitude and influence of Federal science agencies lend profound importance to their ability to perform excellently in all their research activities. Federal support of biomedical R&D, for instance, has increased five-fold since 1960 and now constitutes nearly two-thirds of all such support for the Nation. Thus the general imperative of maintaining excellence in research programs calls special attention to the Federal sector.

Historically, the Federal Government has usually embarked upon scientific enterprises as emergency ventures to meet national crises. Some examples are--

- The creation of the National Academy of Sciences and expansion of the Army Medical Department during the Civil War.
- Establishment of the National Board of Health to combat the yellow fever epidemic of 1878.
- Institution of the Geological Survey of the 1880s.
- Creation of the Hygienic Laboratory, progenitor of the National Institutes of Health, in 1887, to prevent epidemics during heavy waves of immigration.

- Establishment of the National Research Council in order to mobilize science for the first World War.

All were created to perform relatively short-term functions; most were severely curtailed when the urgency had passed.

Few of those Federal agencies encountered the need to maintain excellence in stable organizations, though such fine institutions as the Naval Observatory, the National Bureau of Standards, and the Dept. of Agriculture have long dealt with this problem. The situation has changed as agencies emerged from the second World War with mandates to conduct and support long-term research programs. NIH, NSF and AEC, among others, have faced constraints of slower growth, cutbacks, or social and political pressures, such as rapid shifts in emphasis from one medical problem to another, greatly complicating the task of those endeavoring to stabilize quality at a high level.

The NIH Dual Review System

It might be interesting for present purposes to review how quality control has been achieved in one particular field of science--biomedical investigation--in one Federal agency--the NIH. The apparatus for the selection of NIH grantees has evolved in a spotlight focusing constant attention on accountability to the public on the part of the Government, its advisors, and the scientific community. Some features of the system might usefully be described here, though they are probably generally familiar to many of you.

The NIH peer review system was developed in the 1930s and '40s to evaluate new grant proposals for the National Cancer Institute and those transferred from the wartime Office of Scientific Research and Development.

It came to be a dual review system in 1946, when the National Advisory Councils, created by statute, were administratively supplemented with 21 study sections charged with rating and recommending grant applications according to scientific merit in highly specialized areas. The study sections, now numbering 48, are composed principally of non-Federal scientists grouped by discipline or field. Grant applications are distributed among them irrespective of the Institutes to which they might be assigned for funding.

The emphasis at the study section level of review is on the competence of the applicant and the scientific quality of the proposal, though relevance to NIH missions is also weighed. Quality control in the NIH grant program depends heavily on the expertise and viability of this impartial system of study sections, which has served NIH and the Nation well for nearly 30 years.

Each Institute to which the proposals are centrally assigned is served by a National Advisory Council composed of prominent scientists and civic leaders. Councils charged with advising the Institutes on grants date from the National Advisory Cancer Council established by law in 1937. Each Institute formed since then has an advisory council following the Cancer Institute prototype.

Review of applications by these bodies constitutes the second level of control. Here the recommendations of the study sections are formally acted on. The critical criteria are "program" priority and administrative considerations, such as the distribution of funds among all of the Institute's responsibilities, interests and research opportunities.

It is an important aspect of the laws creating the ten Institutes of NIH that an Advisory Council's approval is requisite to the awarding of all grants (with the recent exception of awards under $35,000 in the Cancer and Heart Institutes). This rule ensures that the impartial winnowing process resulting in recommending grants is not circumvented by political force or other favoritism.

Responsibility for maintaining high scientific quality in NIH grants is largely vested in the peer review system. All awards so processed in fiscal year 1973--including those for research, research training, health manpower education, and construction--totaled $1.5 billion. This included 11,317 biomedical research grants for a total of $815 million. From time to time the NIH dual review system has been under scrutiny or attack. Its defenders do not say it is the only imaginable workable system that would ensure efficiency, objectivity and excellence for a support program of this size and complexity. Other approaches to selection, ranging from bureaucratic choice at the Federal or institutional level to pure randomness, would perhaps serve. However, it is difficult to understand what unmitigated advantages they would offer and how they could command a like measure of respect from the scientific community. This explains why NIH, though lacking complete evidence for objective comparison, defends the present system against drastic change.

The Review of R&D Contracts

Another device for supporting research, much employed by Federal agencies, is the research and development contract.* Since the contract,

*Contracts are not included in the totals above.

as utilized by NIH, differs from the grant in principle, reflecting specifications designed by the payer rather than by the recipient, the controls for each have evolved along different lines. Heretofore, fiscal rather than quality control might often have been stressed in employing contracts. In the interest of scientific excellence, a major objective in NIH programs today is to strengthen contract review.

Development of more stringent quality-control mechanisms for R&D contracts has seemed a wise course in view of the rapid expansion of the contract-funded programs. Over the past decade these have risen from $38 million to $251 million, or from 5 percent to 14 percent of the total extramural programs of the Institutes.* (May I have the first slide please.)

The chart represents all NIH research awards for fiscal years 1967 through 1974. The 1974 projection, based on the '74 President's Budget, would be larger by about $135 million, or 12 percent, if it reflected the actual appropriation, which became law on December 18. The release of funds withheld by the Administration in FY 1973 will add another $128 million.

The right-hand panel shows a percentage distribution of the same data. The trends revealed clearly here reflect an expansion of developmental, or targeted, research on certain prominent health problems--mainly cancer and heart and lung diseases. The Institutes moving in that direction are changing the way they do business. To ensure better quality control, the Institutes are developing systems in which peer review of contracts will parallel that of grants, and will evaluate not only the quality of the proposals but also of the performance and results.

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*Based on awards data for FY 1963-73, excluding BHME.

Maintaining Excellence During Changes in Budget Level

Sudden fluctuations in budget level present difficulties in maintaining the quality of research operations. Sudden increases invite a lowering of standards. Sudden decreases, though they could permit a salutary selectivity, tend in practice more toward dislocation and demoralization. NIH has experienced both kinds of change. During those periods the quality of the extramural programs and awards has remained a paramount consideration.

One of the most precipitous increases in NIH appropriations occurred between fiscal 1956 and 1957, as shown in the next slide (2). The total funds for intra- and extramural programs rose 127 percent--from $74 million to $168 million.* This was due to a policy enunciated by then-Secretary Marion B. Folsom and implemented by the Congress: that no deserving research proposal should be turned down for lack of funds. The chart reflects the budget jump in terms of obligations for R&D, plotted on a log scale. Total R&D obligations rose from $36 million to $75 million.

The increased funds elicited a much larger number of grant applications. There is a uniform impression on the part of staff, viewing the experience in retrospect, that the quality of applications remained high. Evidently the Nation's biomedical science capacity had previously been much underutilized. One would ordinarily expect surges in funding to produce some shift in quality until stability returns at the new level.

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*Excluding Mental Health, Biologics Standards, and other programs that have since been transferred out of NIH.

The sudden augmentation of research grants in 1957 brought other developments. There was a concomitant initiation of a $30 million research construction program and increased training support, in anticipation of national expansion of the biomedical research effort. (Lights, please.)

Decreases in funds available for regular research grants occurred in fiscal 1969 and again in 1970, causing concern for the impact on the entire grant operation. As a temporary measure during fiscal '69, NIH negotiated downward the noncompeting awards--those morally committed for longer than one year. The objective was to recapture money to fund as many new meritorious projects as possible, though at a minimal level.

It was hoped that this practice would not have to be continued beyond that fiscal year, but the President's Budget in the spring of 1969 could offer no relief through fiscal '70. NIH could not continue to favor new grants at the expense of its moral commitment to projects designed to take more than a year to complete. After a thorough reappraisal, it was decided to support the continuing as well as new projects as nearly adequately as possible.

The decrease in research grants from fiscal 1968 to 1970 affected some institutions and departments more than others, causing localized budget crises that sent shock waves through the scientific community. Fortunately the subsequent NIH budget increases have mitigated the very real and demoralizing effects of the 1969 and '70 cuts.

To the science administrator concerned with maintaining excellence, it would be most appealing to work within a long-term budget, but this

is not the way the Federal Government operates. Long-term plans, which NIH produces regularly, must somehow be fitted to the Procrustean bed of annual funding. From the standpoint of institutions, financial stability must come from diversity of support, reserves, and the use of funds least subject to fluctuations to meet long-term needs.

Egalitarianism Vs. Elitism in the Pursuit of Excellence

Science is intrinsically elitist in that it must strive for excellence in the employment of human talent. It must single out and encourage the best minds, which are coincidentally apt to be found in the best institutions. In the case of government-supported science, the presumption is that the taxpayer does not want to pay for mediocrity, or sterile investigation where opportunity is lacking. Tolerance for an "aristocracy of intellect," even in the most egalitarian climate, is anticipated in this endeavor.

The issue of egalitarianism versus elitism in the pursuit of excellence will arise in any science program. However, it seems that Federal programs are especially susceptible to leveling influences--pressures to spread funds geographically, to hire without discrimination, to open meetings to anyone, to place the most emphasis on the health problems that worry the most people. Such laudable aims should all be honored whenever possible. Yet they can pose problems in maintaining productivity and excellence in the scientific effort itself.

By all means let us not deliberately favor any geographic area. But before we distribute research funds by formula according to population or regional need, let us wait until the research *potential* of

all the applicant institutions is equal. Actually, NIH support of research training, construction and resources has indeed tended to increase the scientific capability of institutions and regions throughout the entire country. It is necessary, though, to remind someone occasionally that NIH is not responsible for general uncritical institutional maintenance.

By all means hire without prejudice. Surely this is the only way to obtain the best talent. Here too, this is often a question of the development of potential, but not the support of less than high quality. NIH has initiated several programs designed to increase the capabilities of lower-paid or disadvantaged persons.

By all means open all meetings--to the extent that incoming ideas and criticisms will enrich operations, that those who need to know the proceeding will be informed, that the public will be assured of fairness and integrity. However, the tradeoffs incurred in opening meetings to evaluate grant proposals need careful examination. Many feel that this move would threaten the lifeblood of the scientist--the disclosure of original ideas yet to be tested. Others are concerned about inhibition of the review process, which requires for the most searching evaluations a free and uninhibited exchange within the peer groups.

As you may know, a recent court decision holds that documents in the review process must be publicly available. What effect would this decision have if sustained by the Court of Appeals? Would it deter grant applicants from submitting candid, original proposals?

Would reviewers decline to serve on study panels? What modifications may be necessary in the NIH peer review system? In other areas--those that do not involve privileged information--NIH has opened its meetings and records, and only good seems to have resulted.

By all means let Federal resources be allocated according to the magnitude and gravity of the health problems to be attacked. Apart from the obvious difficulty of developing algorithms for weighing such intangibles as pain and dread, there is an obligation to spend public money in proportion to educated, informed public need and concern. There are two or three serious problems, however, if such an approach is to be strictly or rigidly observed.

First, it would be wasteful to the extent that health-problem weight did not correspond with real research opportunity. The medical sciences altogether can be expected to advance most rapidly if scientists are free to pursue leads as they evolve. On the other hand, bold ventures into unknown territory, even on meager leads, can sometimes be necessary and surprisingly fruitful. Such baffling problems as sudden infant deaths, the demyelinating diseases, and even aging are not devoid of promising new avenues for investigation.

Second, the phenomenon of serendipity is too compelling to be ignored. The unexpected observation or result often reveals new insights and new paths to explore that were unforeseen in the original research design. This argues for a judicious opportunism--a readiness to invest in pursuits that attract the scientist on an intuitive or esthetic basis, in expectation of the useful unexpected, and to encourage changes of direction as new leads are thus revealed.

Finally, there exists the related dependence of progress in any area upon the more general extant state-of-the-art. Open-heart surgery is an oft-cited example of a realm that could not have been breached until anesthesiology, antisepsis, and other technologies had advanced to a certain requisite stage. The development of tissue culture as a means of cultivating virus for vaccine production was a vital preliminary to the conquest of polio. An example extending beyond pure biomedical science, but soon to serve the clinician and the public, is the use in artificial organs of atomic-powered and miniaturized devices developed in military and space research. Examination of the broader field of chemistry would yield innumerable examples of benefits later and unexpectedly occuring to advance clinical medicine.

All of these considerations urge the support of research and development on a very broad front as a rational approach to medical advancement. This crucial aspect must not be overlooked in the attraction to attack health and disease problems head-on.

The allocation of resources within medical research is a complex process more responsive to social than scientific criteria--more subjective than objective. This is not entirely amiss. However, the extent and significance of research opportunity should weigh heavily in decisions on where to place funds if maximum progress is to be made in medical science generally.

An administrator deals with human beings as well as with their products or accomplishments. The elitism essential to excellence must not induce the science administrator, if he hopes to attract and lead

capable people, to sacrifice reasonableness and humanitarianism. If he does, excellence will surely escape him. This issue arises especially in the case of the superannuated investigator--the familiar problem of the stone that has ceased to roll and is gathering moss. Every science administrator has faced this, and must deal with it individually. It is consoling that when some of us reach the point of diminishing returns in original investigation, we can still contribute as science administrators. Unhappily, however, this is not true of all, and a very real problem remains. In Federal employment, incentives to earlier or gradual retirement are probably a saving in the long run. More career flexibility--permitting voluntary lateral motion into less demanding teaching, administration or, in industry, production and distribution--might prove economical and extremely important in preserving excellence in the science laboratories, whether on university campuses or in government.

The Science Administrator: Czar or Manager?

My personal view of the role of the science administrator is that he can be most effective if he takes the role of a manager or steward rather than that of a czar. There is, I am certain, no room for authoritarianism in science administration: the nature of the enterprise precludes it. The *necessary* freedom of the basic investigator to go where his work leads is reason enough. Developmental research might call for more involvement at the substantive level, but even then there are unknowable limits to how hard and fast the process can be driven. Of course, one does always face the necessity for hard

decisions in the allocation of resources, and those must be as judicious and well informed as humanly possible.

The science administrator's principal function is to develop a structure and an atmosphere in which scientists can work productively and to delegate responsibility wisely to those who will most actively pursue the agency's missions. Excellence of the organization and its product will follow if he has done this well.

Research Institutions and the Scientific Community

By way of conclusion, we might consider broadly the supportive research institution and its relationship to the scientific community, with particular reference to a mutual dedication to excellence. There are inherent tensions between science--with its need for freedom, its complex and esoteric subject matter, its loyalties to transcendant disciplines--and the institutions that seek to employ science in pursuit of their missions: tensions reflecting the propensity of institutions to drive their operations, tally their progress, and justify themselves in cost-benefit terms.

NIH--to return to our example--is no exception. Moreover, it is a Federal enterprise with certain rigidities peculiar to the Federal establishment. But it is an institution that has evolved along lines that endow it with remarkable abilities to house and support science, and to turn it to social purpose.

Through that portion of its role which is to be an agent or broker between the scientific community and the superstructure of

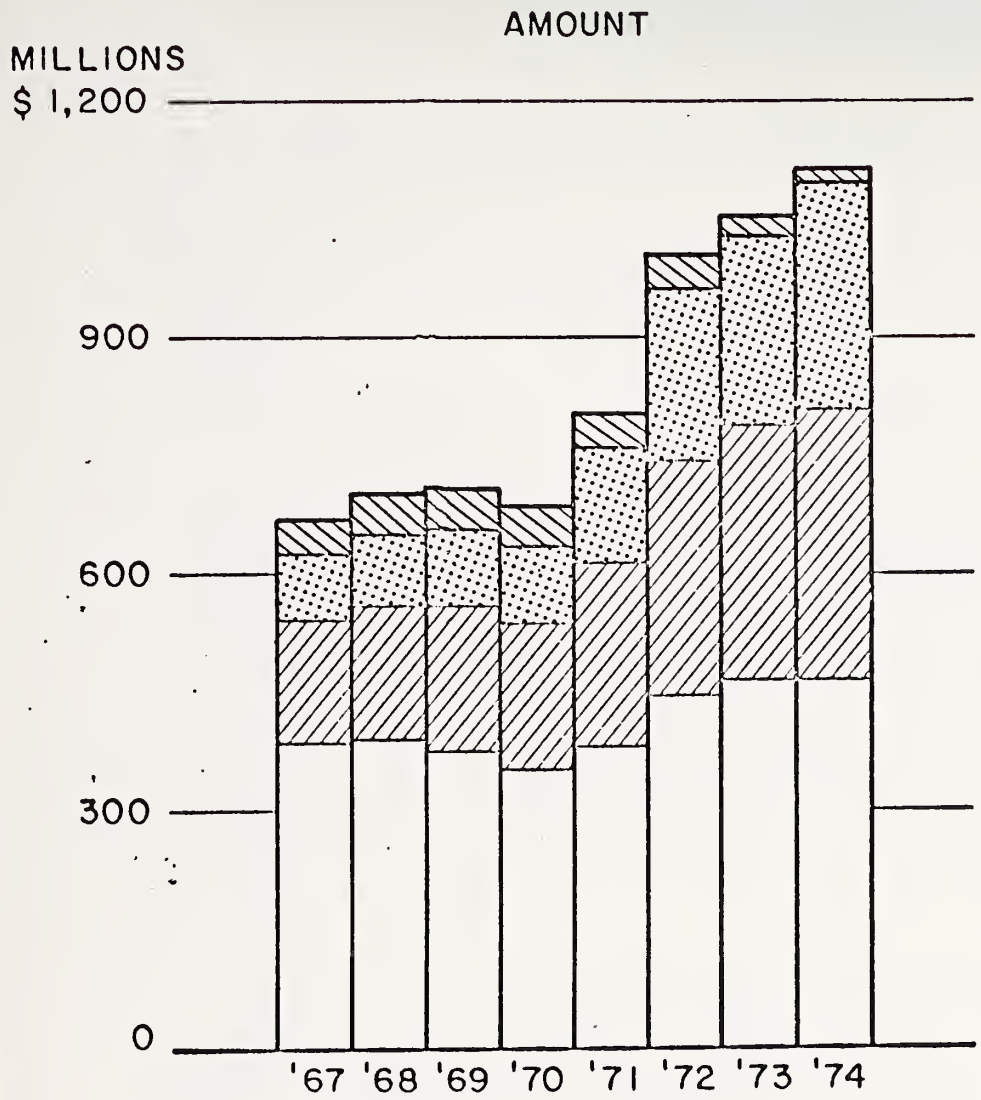
government--that amorphous body which ultimately reflects the public will--NIH has succeeded in funneling sizable sums of public treasure into the study of dread diseases. Through its dual review system, which maximizes the participation of the scientific community in fund distribution, it has managed to do this equitably and productively with a minimum of energy loss through friction. These, at least, are my perceptions from past experience and after a brief time in the Federal environment.

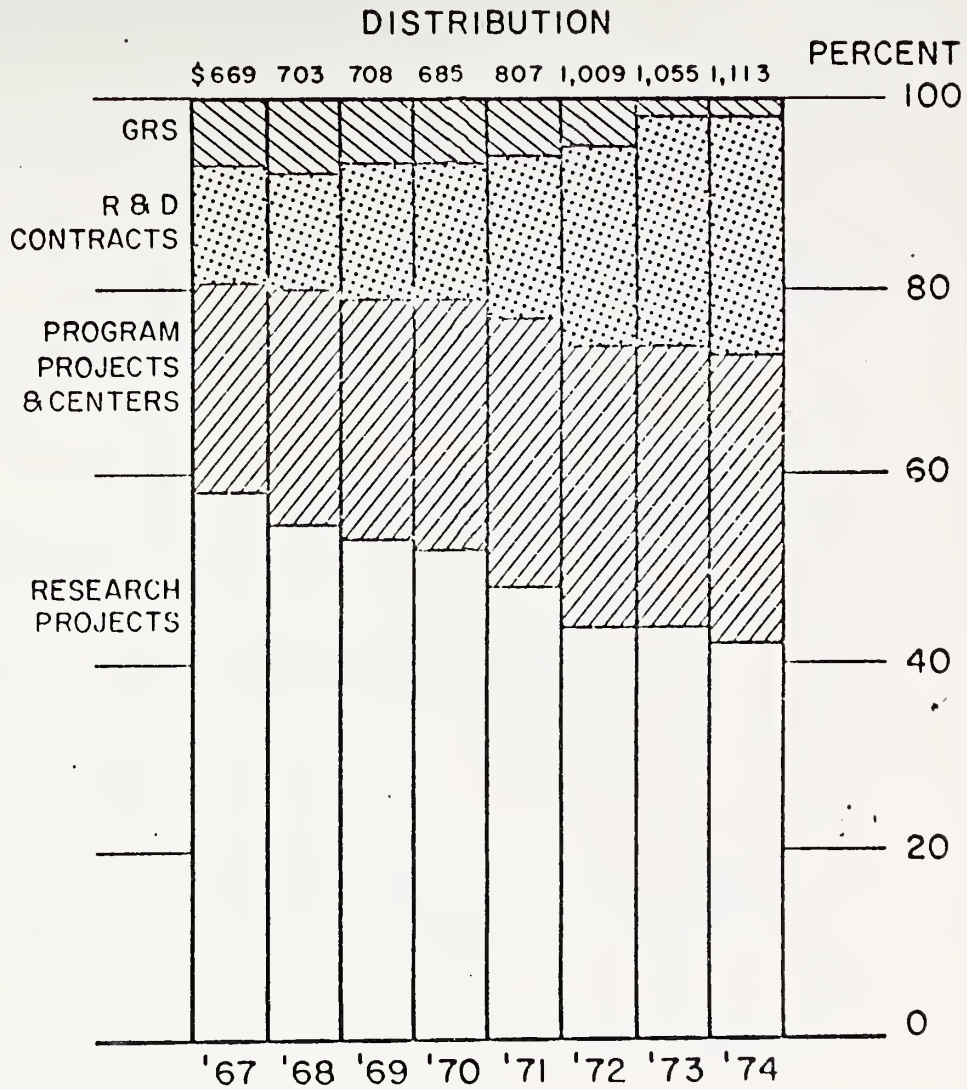
Another perception is that research organizations need more guidance and support from the scientists themselves--not strictly in the sense of political support, though that does help, but in the broader sense of assistence in informing the public of what science and its institutions do and require. Scientists might also contribute more, through responsible societies and other private groups, to the formulation of public policy, expressing their views on controversial issues. There is no escaping the fact that science as it now exists in this country is part of a societal process. To the extent that we wish to see it thrive, with excellence wherever possible, we must become involved.

Slide 1

NIH EXTRAMURAL RESEARCH PROGRAM AWARDS AND THEIR PERCENT DISTRIBUTION

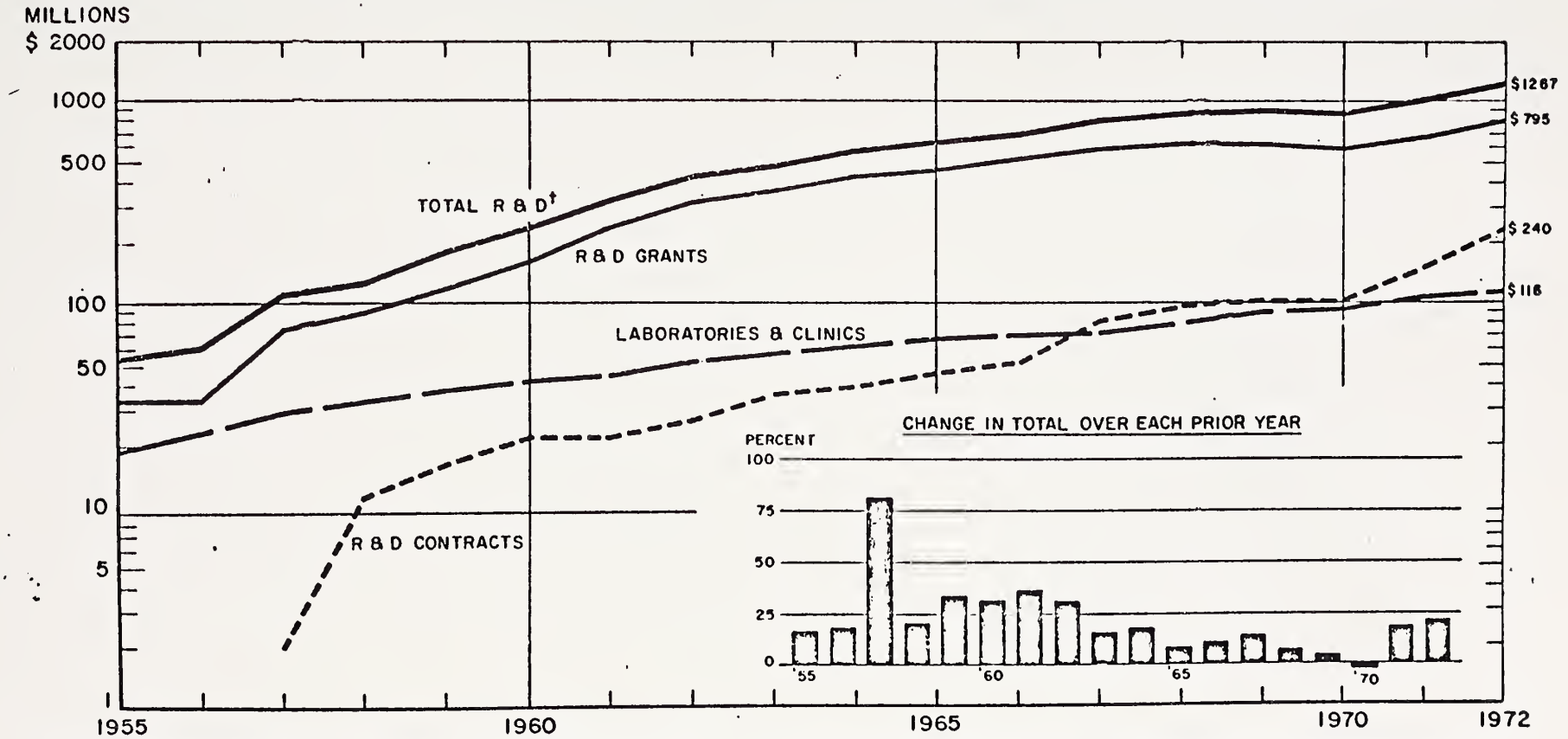
FISCAL YEARS 1967 – 1974 EST.





Slide 2

NIH FUNDS OBLIGATED FOR RESEARCH AND DEVELOPMENT, FISCAL YEARS 1955-1972*



*EXCLUDING CONSTRUCTION AND PROGRAMS TRANSFERRED OUT OF NIH. †R & D GRANTS, R & D CONTRACTS, LABORATORIES & CLINICS, COLLABORATIVE PROGRAMS, FIC, FOREIGN CURRENCY PROGRAMS, BIOMETRY/EPIDEMIOLOGY/FIELD STUDIES, AND PROGRAM MANAGEMENT APPLICABLE TO R & D.

TAB 5

NOTES TO ACCOMPANY CHARTS ON NIH ORGANIZATION AND FUNCTIONS

AAAS Meeting
San Francisco
3/1/74

Dr. Robert S. Stone
Director, NIH
Bethesda, Md.

NOTE: These cards are dated to correspond with new charts not yet available. The slides accompanying them, though the latest we have, are last year's. Thus the cards will serve to update the charts being shown.

Two exceptions: Charts 61 and 149 are up-to-date. (Dr. Sherman is planning to use 61.)

CHART 17

THE MISSION OF NIH

To advance the health and well-being of the American people through support of--

- Research into the biological phenomena underlying health and disease--

  (1) To provide a better product for the health-care system to deliver,

  (2) To reduce costs through definitive solution of health problems.

- Training for biomedical investigation

- Institutions engaged in medical research and education (mainly GRS grants and NCI construction).

- Biomedical communications (mainly NLM).

CHART 149

NIH ACCOUNTS FOR--

8% of all Federal R&D; 40% of Federal funds for R&D at educational institutions; 37% of Federal funds for academic science (defined as R&D, training, facilities, and resources).

Shows the relative importance of NIH among Federal agencies, particularly with respect to higher education. NIH continues to support strongly the Nation's biomedical research plant.

Compare the 8% of all Federal R&D with the 40% of R&D in the schools.

DHEW accounts for about half of Federal support of academic science; NSF plus DHEW, for about two-thirds.

CHART 9E

ORGANIZATION OF NIH

This shows the present organization of NIH into 10 institutes, the National Library of Medicine, and 6 research and service divisions.

NCI, NHLI, and NLM have "bureau" status. For NCI, this implies budget autonomy.

The health-related agencies of the Department include (besides NIH): the Food and Drug Administration; the Alcohol, Drug Abuse, and Mental Health Administration; the Center for Disease Control; the Health Services Administration; and the Health Resources Administration.

All these agencies except NIH and FDA were created in 1973. A former bureau of NIH--Manpower Education--has been decentralized and is no longer an NIH responsibility.

CHART 16

TYPICAL INSTITUTE OF NIH

Shows general functions common to all categorical institutes, forming a broad base for program activities.

Advisory groups: National Advisory Councils for extramural activities, Boards of Scientific Counselors for intramural.

Collaborative studies, usually financed by contracts, have expanded in recent years, are expected to grow more. Present effort to develop peer review mechanisms to ensure same degree of quality control as with grants.

Trend toward development of highly active operations that cross these lines--extramural, intramural, collaborative.

CHART 34

MEDICAL R&D AS A PROPORTION OF TOTAL HEALTH COST, U.S., 1960 AND 1973

As the Nation's total expenditure for health--doctors, hospitals, drugs, research, insurance, etc.--has increased since 1960, medical R&D has increased faster.

It has risen from about $845 million to $3.5 billion, or from 3% to 4% of the total health cost, now estimated at $94 billion.

Over this period the Federal support of medical research has risen from 1.7% of the total health cost to about 2.4%.

CHART 27

MEDICAL R&D AS A PROPORTION OF TOTAL R&D COST, U.S., 1960-1973

NIH plays a leading role in the Nation's medical R&D.

All U.S. medical and health-related research has grown from about $845 million in 1960 to $3.5 billion in 1973.

Thus it has doubled as a proportion of all R&D, rising from 6 to 12 percent. Bulk of R&D is national defense program.

The two coins show where the $3.5 billion comes from and where it is spent. The Government, contributing nearly a third of all the funds, accounts for only a sixth of the research.

Academia and industry performed about the same share in 1973--34 percent.

CHART 24 FUNDS FOR MEDICAL R&D BY SOURCE, U.S., 1961-73 EST. (Federal vs. non-Federal support at 3-year intervals)

Non-Federal sources of research funds exceeded Federal until the early 1950s.

In 1973 Federal support will be about $2.2 billion against non-Federal $1.3 billion, totaling $3.5 billion. NIH--$1.3 billion, 60% of Federal. Bulk of research, however, is conducted in schools, hospitals, and other nonprofit, non-Federal institutions.

Note that private support continues to rise despite taxpayers' support through government. May be mutually stimulating.

Non-Federal support is from industry, private foundations and health agencies, other private sources, State and local governments. Industry in 1973 is estimated at $1 billion.

CHART 26 NIH FUNDS AS A PROPORTION OF NATION'S MEDICAL R&D, EST. 1973 AND 1974

Latest estimates of total medical R&D support for the Nation are $3.5 billion for 1973 and $4.1 billion for 1974.

In fiscal 1973, NIH R&D obligations totaled $1.3 billion. This is expected to rise to $1.7 billion in 1974--from about 38% to 42 percent.

Other Federal sources in 1973 are estimated at $896 million. These include DHEW (other than NIH) $270 million, DoD $125, AEC $111, VA $74, Transportation $65, NSF $45, Interior $44, and NASA $42. This total will rise to $992 million in 1974.

Industry will rise slightly, from $1.0 to $1.1 and drop from 29 to 27 as a percent of the total.

Other non-Federal will remain about the same, rising from $283 to $289 million.

CHART 61

NIH OBLIGATED FUNDS BY FUNCTION, FY 1955-74 EST.

NIH functions include both the support of research and the development of biomedical scientists and institutions.

"Research," about 80% of the program, includes direct and collaborative activities, regular grants, general research support grants, and special grants (program projects and centers).

Total grants comprised 66% of all NIH funds in '73; will account for 64% in '74. R&D contracts (mostly in collaborative programs) accounted for 17% of all NIH funds in '73 and will rise to 17.5% this year. "Research construction grants," once a $100 million program, now includes only cancer construction--$34 million in FY '74.

Estimated obligations for FY '74 includes funds impounded in '73 and now available, and funds appropriated. We expect to obligate the entire $2,022 million before July 1.

CHART 57

NIH FUNDS OBLIGATED FOR RESEARCH AND DEVELOPMENT, FY 1955-1973

This chart represents the R&D obligations of NIH on a log scale over time. "Total R&D" includes all R&D programs. Three of these are represented by the other curves--R&D grants, labs & clinics, R&D contracts.

The sharp change in R&D grants between FY 1956 and '57 reflects an increase of more than 75 percent--as revealed in the inset. Labs & clinics--the intramural research program--has enjoyed a gradual rise and much stability. R&D contracts is the fastest growing program.

For FY 1973 R&D contracts totaled $250 million, labs & clinics $120, R&D grants $815, and all NIH $1,322.

TABLE 1 — NIH BUDGET AUTHORITY BY PROGRAM, FY 1973-75

Working back from FY 1975 President's Budget, comparable columns are shown for FY '74 and '73. Comparable in that--

- Funds withheld in '73 and released for '74 are shown in the '73 column,
- Formula grants to institutions (GRS) are treated as though appropriated to DRR in '73 rather than drawn from institute funds,
- Other, lesser adjustments have been made.

We see major increases over the 3 years for Cancer and Heart, a minor increase for Eye, a considerable drop for DRR. The other programs either decrease moderately or stay about the same.

From '73 to '75, total NIH funds increase $69 million.

TABLE 2 — NIH BUDGET AUTHORITY BY MECHANISM, FY 1974-75

Here the same budget for FY 1974 and '75 is arranged by mechanism of support.

We see major decreases for General Research Support grants (86%)--an endangered species--and for Research Training Grants (37%). There is some drop in Cancer Construction (20%).

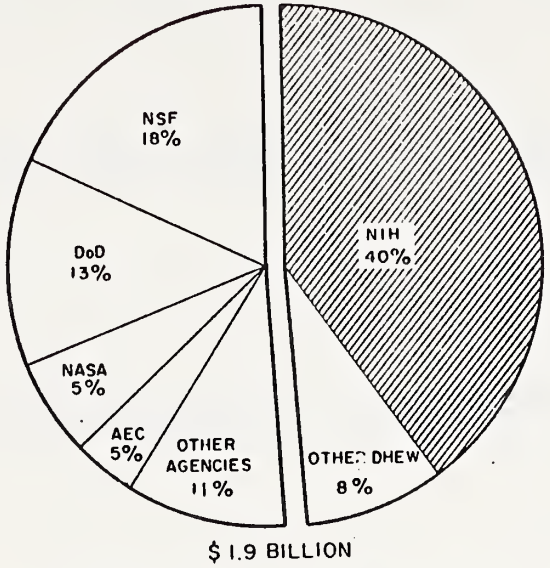
Major increases are planned for Other Research Grants (mostly program projects, centers, and resources grants) (15%), R&D Contracts (10%). Fellowships (53%), and Cancer Control (32%).

The other changes are all minor increases.

There is a 3% increase in the total.

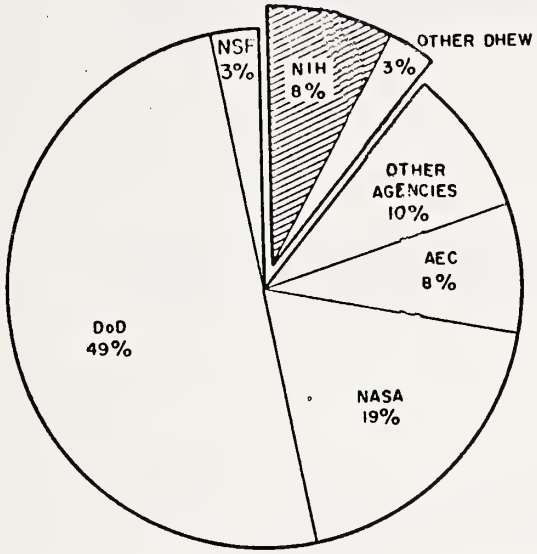
NIH ACCOUNTS FOR–

40% OF FEDERAL FUNDS FOR R & D AT EDUCATIONAL INSTITUTIONS



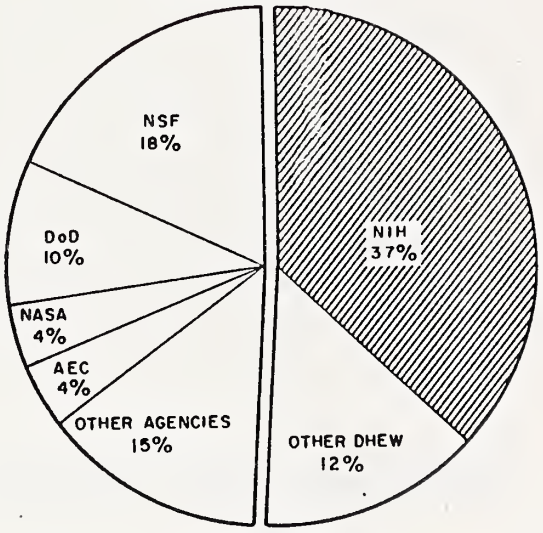
$1.9 BILLION

8% OF ALL FEDERAL R & D



$17.0 BILLION

37% OF FEDERAL FUNDS FOR ACADEMIC SCIENCE†



$2.5 BILLION

FEDERAL SUPPORT, FY 1973 EST (IN MILLIONS)

AGENCY	R & D	EDUC. INSTITUTIONS*	
		R & D	ACADEMIC SCIENCE†
TOTAL	$16,976	$1,890	$2,521
DHEW	1,818	904	1,225
NIH	1,322	749	933
OTHER	496	155	292
NSF	462	340	450
DoD	8,362	255	255
NASA	3,200	103	111
AEC	1,358	87	96
OTHER	1,776	201	384

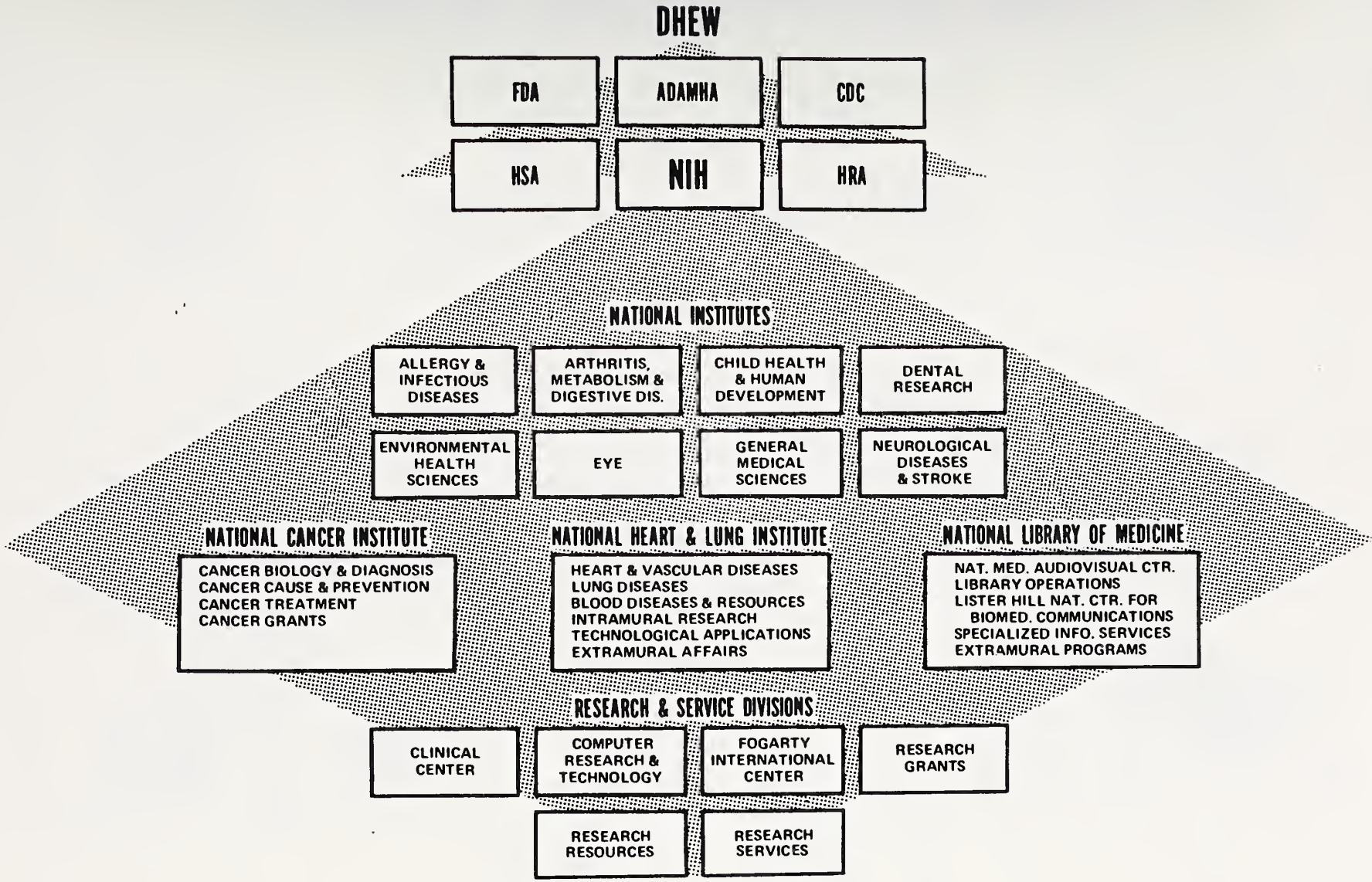
SOURCE: NSF AND NIH

*ESTIMATED. †R & D, TRAINING, FACILITIES, RESOURCES.

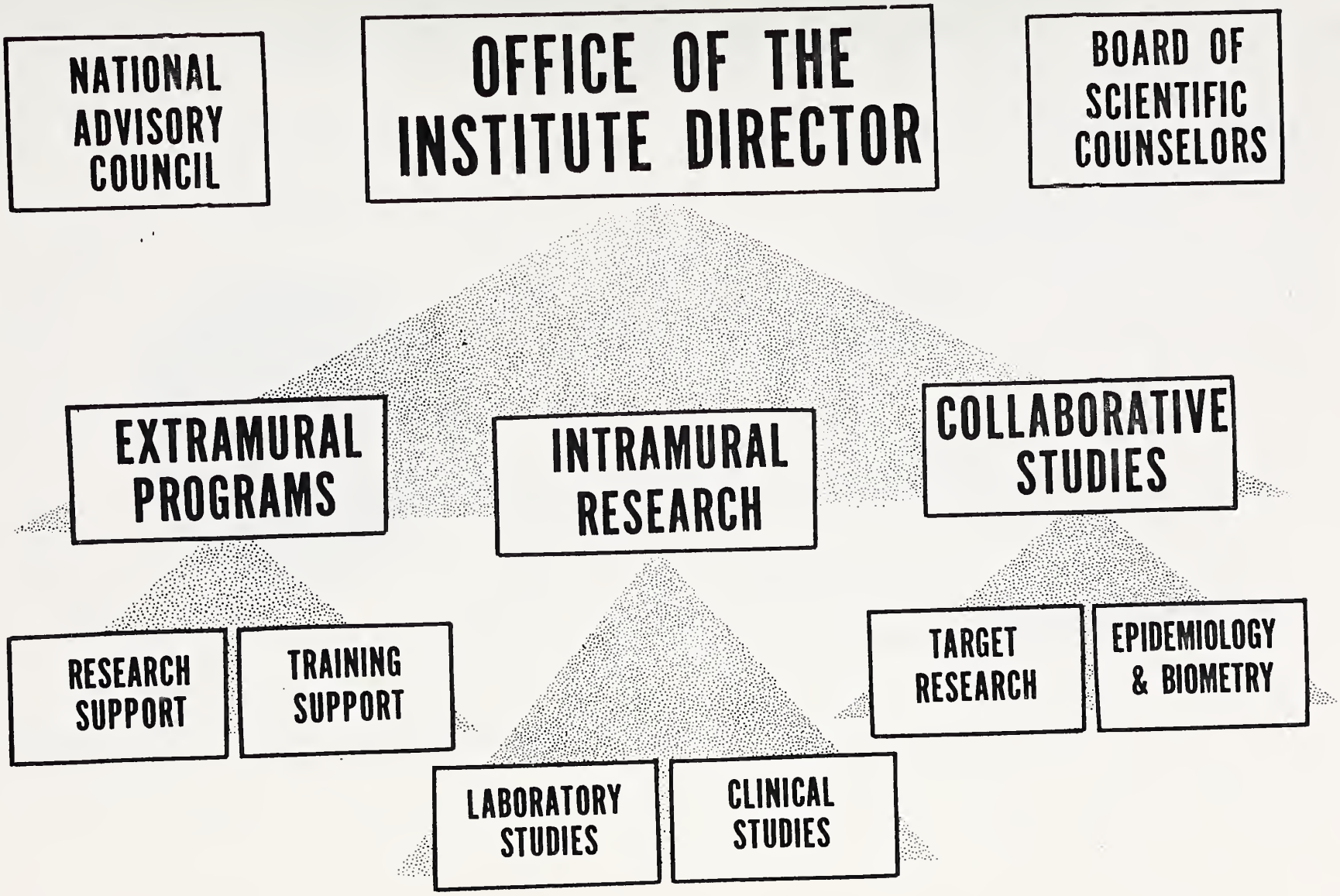
THE MISSION OF NIH

TO ADVANCE HEALTH AND WELL-BEING THROUGH SUPPORT OF —

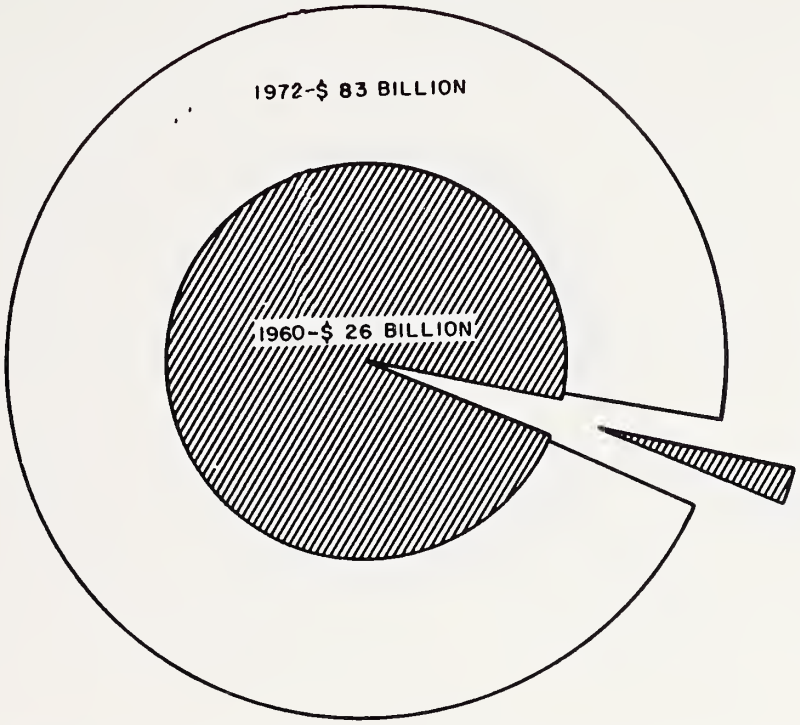
- *RESEARCH* on the diseases of man
- *TRAINING* of biomedical scientists
- *INSTITUTIONS* engaged in medical research and education
- *BIOMEDICAL COMMUNICATIONS*


DHEW
FDA
ADAMHA
CDC
HSA
NIH
HRA
NATIONAL INSTITUTES
ALLERGY & INFECTIOUS DISEASES
ARTHRITIS, METABOLISM & DIGESTIVE DIS.
CHILD HEALTH & HUMAN DEVELOPMENT
DENTAL RESEARCH
ENVIRONMENTAL HEALTH SCIENCES
EYE
GENERAL MEDICAL SCIENCES
NEUROLOGICAL DISEASES & STROKE
NATIONAL CANCER INSTITUTE
CANCER BIOLOGY & DIAGNOSIS
CANCER CAUSE & PREVENTION
CANCER TREATMENT
CANCER GRANTS
NATIONAL HEART & LUNG INSTITUTE
HEART & VASCULAR DISEASES
LUNG DISEASES
BLOOD DISEASES & RESOURCES
INTRAMURAL RESEARCH
TECHNOLOGICAL APPLICATIONS
EXTRAMURAL AFFAIRS
NATIONAL LIBRARY OF MEDICINE
NAT. MED. AUDIOVISUAL CTR.
LIBRARY OPERATIONS
LISTER HILL NAT. CTR. FOR BIOMED. COMMUNICATIONS
SPECIALIZED INFO. SERVICES
EXTRAMURAL PROGRAMS
RESEARCH & SERVICE DIVISIONS
CLINICAL CENTER
COMPUTER RESEARCH & TECHNOLOGY
FOGARTY INTERNATIONAL CENTER
RESEARCH GRANTS
RESEARCH RESOURCES
RESEARCH SERVICES

TYPICAL INSTITUTE OF NIH



MEDICAL R & D AS A PROPORTION OF TOTAL HEALTH COST
UNITED STATES, 1960-1972



MEDICAL RESEARCH & DEVELOPMENT

$ 845 MILLION-3% OF 1960 TOTAL HEALTH COST

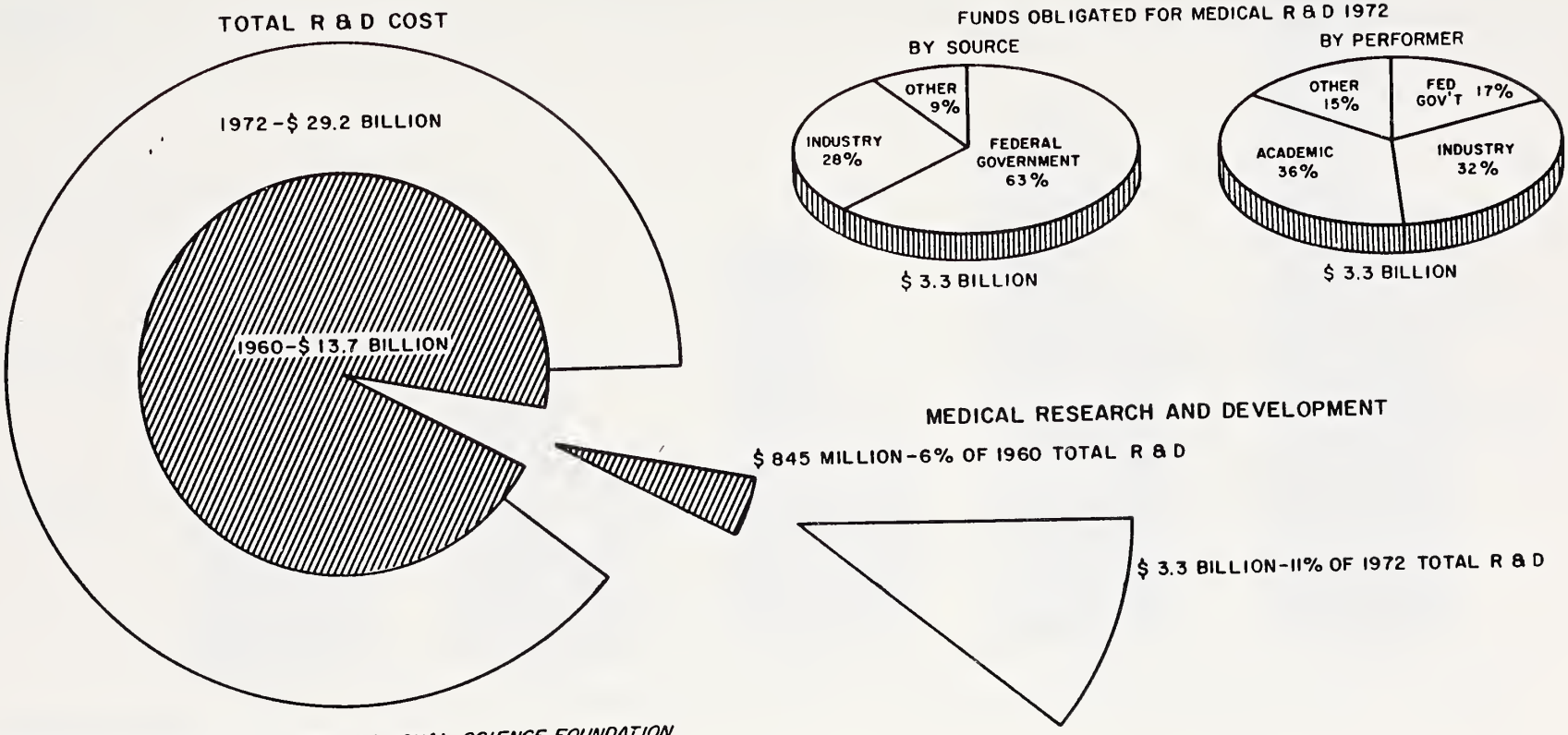
$ 3.3 BILLION-4% OF 1972 TOTAL HEALTH COST

NATIONAL HEALTH COST, 1972
(IN BILLIONS)

TOTAL	$ 83.4
HOSPITAL & NURSING-HOME CARE	36.0
PHYSICIANS', DENTISTS', AND OTHER PROFESSIONAL SERVICES	22.8
DRUGS, APPLIANCES & OTHER EXPENSES	18.5
CONSTRUCTION	4.1
RESEARCH	2.0

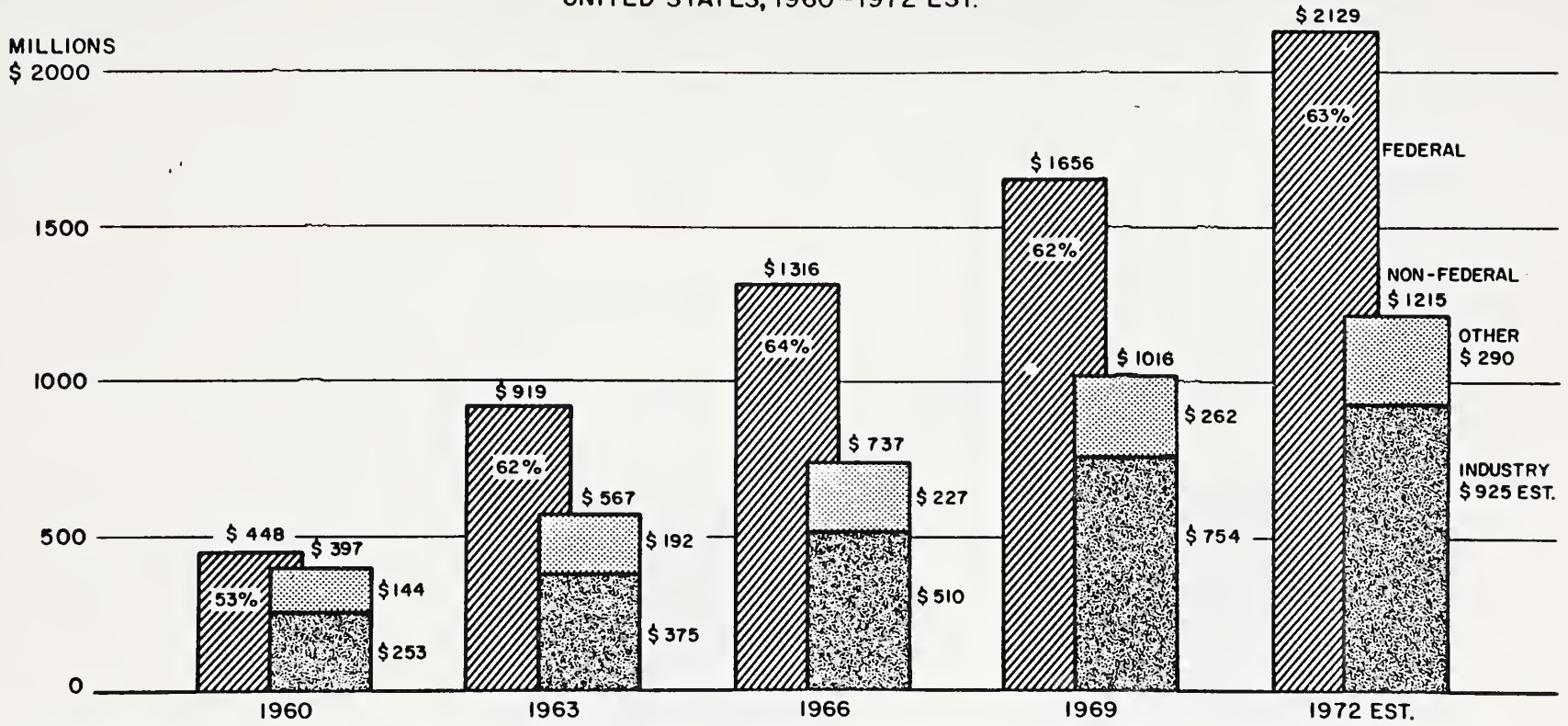
SOURCE FOR NATIONAL HEALTH COST: *SOCIAL SECURITY BULLETIN, VOL. 36, NO. 1, JANUARY 1973.*

MEDICAL R & D AS A PROPORTION OF TOTAL R & D COST
UNITED STATES, 1960-1972


TOTAL R & D COST
1972 - $ 29.2 BILLION
1960 - $ 13.7 BILLION
FUNDS OBLIGATED FOR MEDICAL R & D 1972
BY SOURCE
OTHER 9%
INDUSTRY 28%
FEDERAL GOVERNMENT 63%
$ 3.3 BILLION
BY PERFORMER
OTHER 15%
FED GOV'T 17%
ACADEMIC 36%
INDUSTRY 32%
$ 3.3 BILLION
MEDICAL RESEARCH AND DEVELOPMENT
$ 845 MILLION - 6% OF 1960 TOTAL R & D
$ 3.3 BILLION - 11% OF 1972 TOTAL R & D

SOURCE FOR TOTAL R & D COST: *NATIONAL SCIENCE FOUNDATION.*

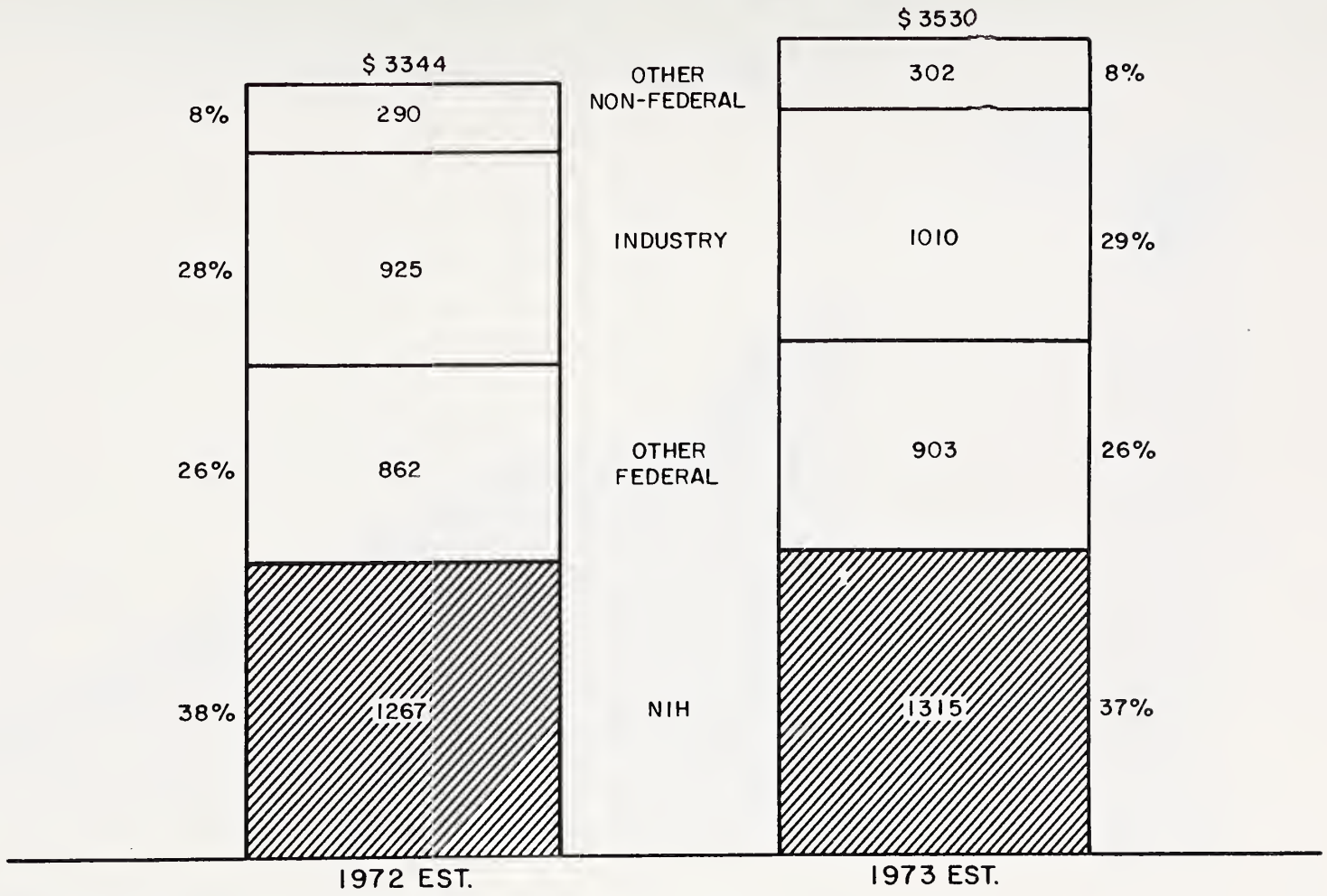
FUNDS FOR MEDICAL R & D BY SOURCE*
UNITED STATES, 1960–1972 EST.



* COVERS ONLY MEDICAL AND HEALTH-RELATED R & D — NO TRAINING OR CONSTRUCTION. NON-FEDERAL DATA SINCE 1964 ARE NOT STRICTLY COMPARABLE WITH THOSE FOR PRIOR YEARS, AS COVERAGE HAS BEEN IMPROVED.

NIH FUNDS AS A PROPORTION OF NATION'S MEDICAL R & D*

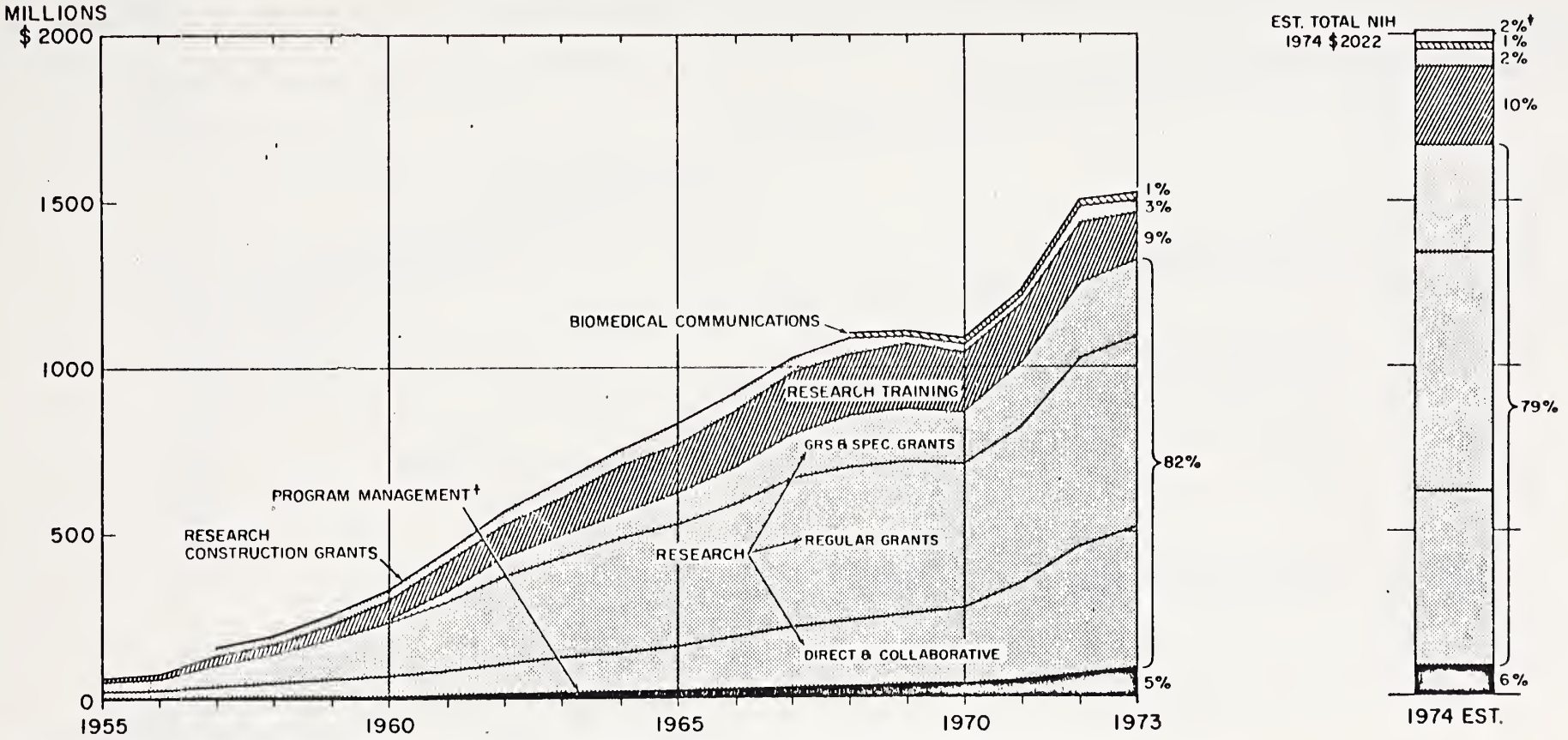
EST. 1972 AND 1973 (IN MILLIONS)



* COVERS ONLY MEDICAL AND HEALTH-RELATED R & D — NO TRAINING OR CONSTRUCTION.

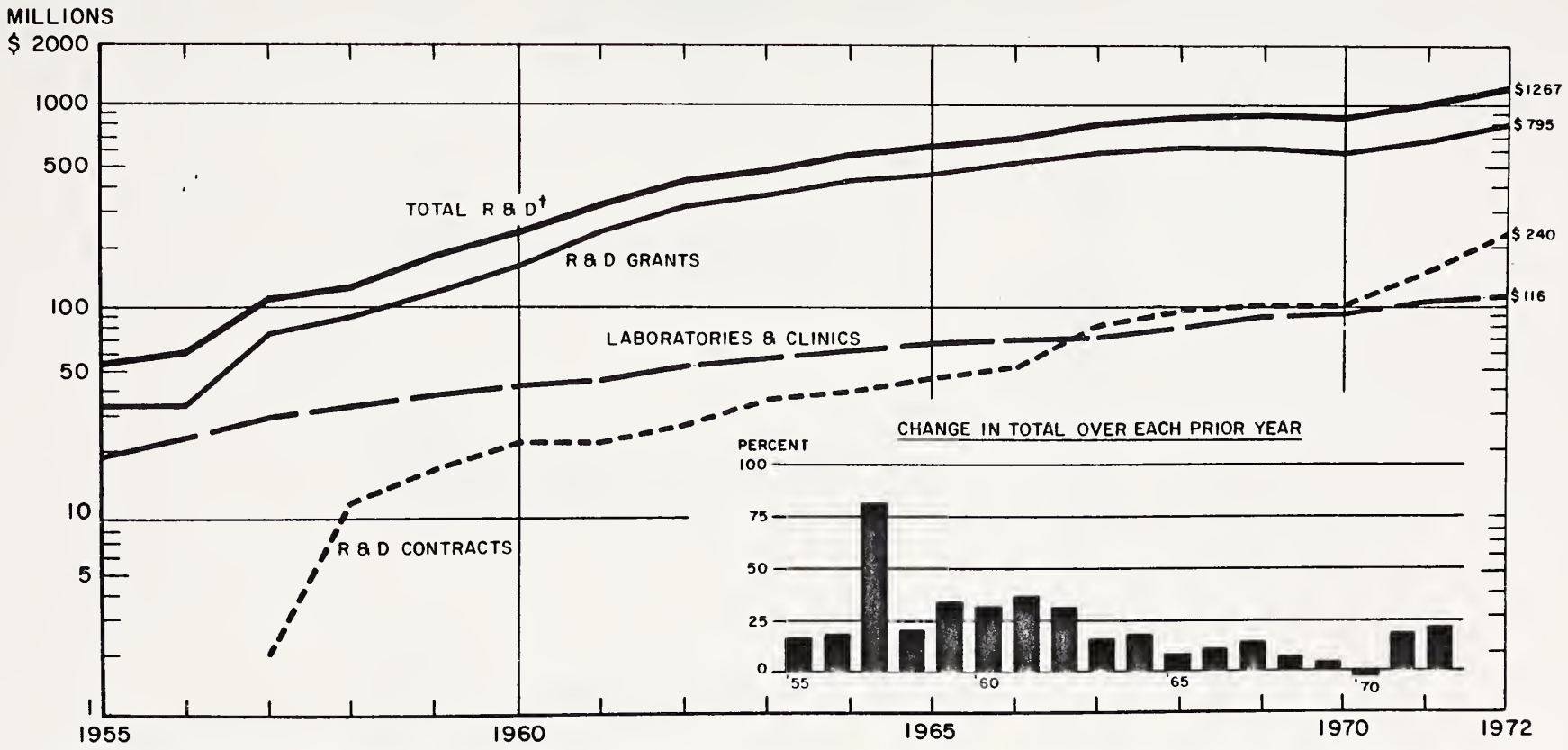
NIH OBLIGATED FUNDS BY FUNCTION, FY 1955-1974 EST.

EXCLUDING PROGRAMS THAT HAVE BEEN TRANSFERRED OUT *



* NIMH, COMMUNITY PROGRAMS, DBS AND BHME. ALSO EXCLUDES FOREIGN CURRENCY PROGRAM. INCLUDES NLM FROM FY 1968 ON.
† INCLUDES BUILDINGS AND FACILITIES FROM FY 1969 ON. BUT CHART EXCLUDES DIRECT CONSTRUCTION FOR PRIOR YEARS. ‡ CANCER CONTROL.

NIH FUNDS OBLIGATED FOR RESEARCH AND DEVELOPMENT, FISCAL YEARS 1955-1972*



*EXCLUDING CONSTRUCTION AND PROGRAMS TRANSFERRED OUT OF NIH. †R & D GRANTS, R & D CONTRACTS, LABORATORIES & CLINICS, COLLABORATIVE PROGRAMS, FIC, FOREIGN CURRENCY PROGRAMS, BIOMETRY/EPIDEMIOLOGY/FIELD STUDIES, AND PROGRAM MANAGEMENT APPLICABLE TO R & D.

NATIONAL INSTITUTES OF HEALTH
BUDGET AUTHORITY, FY 1973-75
By Program

Program	FY 1973 (comparable)	FY 1974 (comparable)	FY 1975 President's Budget
Cancer	$ 485.2	$ 527.4	$ 600.0
Heart	287.9	286.7	309.3
Dental	45.8	43.9	44.0
Arthritis	158.3	153.1	153.0
Neurology	124.5	120.0	120.0
Allergy	107.7	110.5	110.4
General	173.8	166.8	168.3
Child Health	126.0	125.0	124.9
Eye	36.8	40.0	39.9
Env. Health	30.3	28.3	28.7
DRR	135.8	126.9	82.7
FIC	4.6	4.8	4.8
NLM	28.4	26.3	27.7
Other	20.4	21.0	21.1
Total	$1,765.5	$1,780.7	$1,834.8

NATIONAL INSTITUTES OF HEALTH
BUDGET AUTHORITY, FY 1974-75
By Mechanism

Mechanism	FY 1974 (comparable)	FY 1975 President's Budget
Research programs	$1,471.7	$1,530.4
Regular grants	684.8	706.8
GRS grants	52.2	7.3
Other res. grants	237.8	273.5
Labs & clinics	155.6	165.3
R & D contracts	296.0	325.8
Other direct res.	45.3	51.7
Research training	137.0	122.3
Grants	96.9	61.1
Fellowships	40.1	61.2
Cancer construction	27.5	22.0
Cancer control	34.1	45.1
NLM	26.3	27.7
Program management	63.1	66.2
Other	21.0	21.1
Total	$1,780.7	$1,834.8

BACKGROUND INFORMATION ON THE ORGANIZATION AND BUDGET OF THE NATIONAL INSTITUTES OF HEALTH [1]

Robert S. Stone, M.D.[2]

		Page
I.	Organization of the National Institutes of Health	1
II.	The Current Year (Fiscal 1974) Budget	3
III.	1975 Budget Authority	3
IV.	Federal Budgets for Medical R&D, FY 1971-74	6
V.	Legislation and Pending Bills	7

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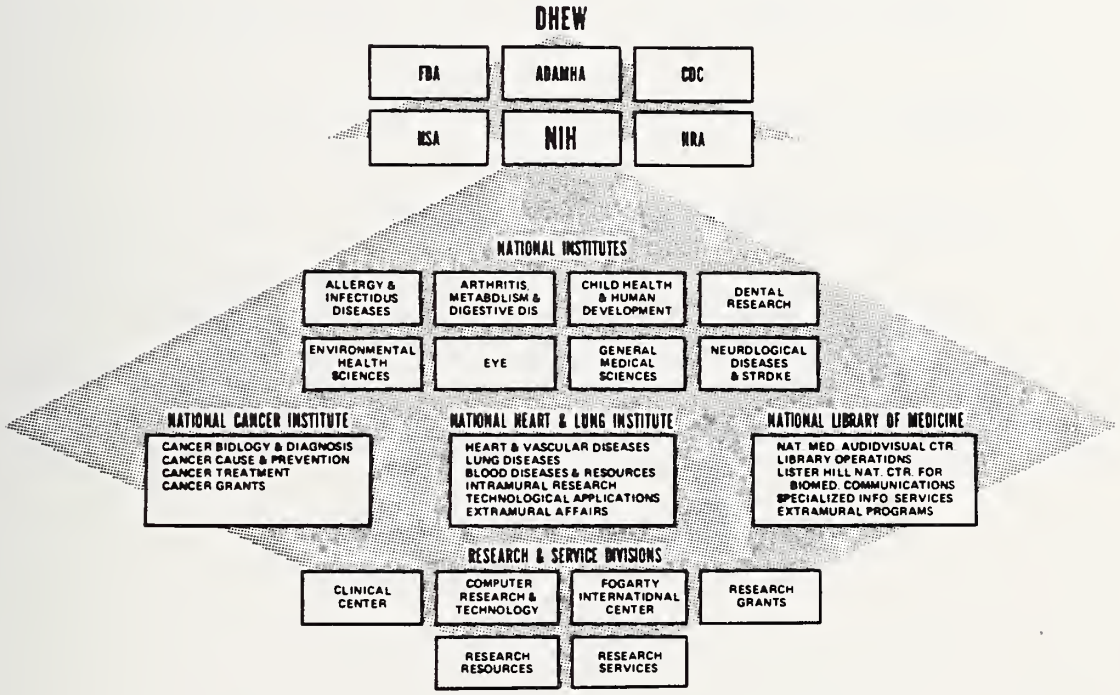
1 Prepared for presentation at the Annual Meeting of the Federation of American Societies for Experimental Biology, Atlantic City, N.J., April 6-12, 1974.

2 Director, National Institutes of Health, Public Health Service, U.S. Department of Health, Education, and Welfare.

I. ORGANIZATION OF THE NATIONAL INSTITUTES OF HEALTH



Principal Officers, National Institutes of Health:

Director	Dr. Robert S. Stone
Deputy Director	(vacant)
Deputy Director for Science	Dr. DeWitt Stetten, Jr.
Assistant Director for Intramural Affairs	Dr. Philip S. Chen, Jr.
Associate Director for Collaborative Research	Dr. Leon Jacobs
Associate Director for Extramural Research and Training	Dr. Thomas E. Malone
Associate Director for Program Planning and Evaluation	Dr. Thomas J. Kennedy, Jr.
Associate Director for Clinical Care	Dr. Robert S. Gordon
Associate Director for Administration	Mr. Leon M. Schwartz
Associate Director for Communications	Mr. Storm Whaley

The 1974 Labor-HEW Appropriation Act (Public Law 93-192, dated December 18, 1973) provides $1,859,771,000 for the National Institutes of Health (NIH). The Act also includes a proviso which permits the Administration to allocate up to 5% less than the amounts appropriated for DHEW. As a result of this provision the NIH has been apportioned $1,784,845,000, or a reduction of about 4.8%, from its 1974 appropriations. In addition to the above, 1973 impounded funds totalling more than $239 million have been released for obligation in fiscal year 1974.

The tables that follow show: (a) the 1975 budget as compared with the 1974 budget authority, and (b) an appropriation summary for fiscal years 1973 through 1975. The amounts for budget authority in 1973 and 1974 may deviate slightly from actual figures since they have been made comparable to the 1975 estimate.

III. 1975 BUDGET AUTHORITY
(In thousands of dollars)

	1974	1975 Request	Change over 1974
Research Institutes & Divisions			
Research grants	$974,825	$987,544	+$12,719
Training programs	137,040	122,270	-14,770
Laboratory and clinical research	155,618	165,257	+9,639
Research and development contracts	295,987	325,821	+29,834
Other direct operations	108,406	117,932	+9,526
Cancer control program	34,055	45,098	+11,043
Cancer construction	27,550	22,000	-5,550
Subtotal, Institutes & Divisions	1,733,481	1,785,922	+52,441
National Library of Medicine	26,254	27,738	+1,484
Other	20,993	21,124	+131
Total, NIH	1,780,728[1/]	1,834,784[1/]	+54,056

1/ Includes Cancer Research Initiative of $527,399,000 in 1974 and $600,000,000 in 1975.

Highlights of the 1975 Budget

The President's 1975 budget for NIH provides an overall net increase of $54 million.

1. Research: The request represents a net increase over 1974 of $52.4 million. The major features of the budget for research are:

   a. An increase of $72.6 million in cancer research for the continuation and expansion of the cancer research initiative in accordance with the National Cancer Program Plan.

   b. An increase of $22.6 million in heart and lung research including $7.6 million for heart and vascular diseases; $7.4 million for lung disease and $5.3 million for blood diseases and resources.

   c. A decrease of $45.2 million representing the decision to discontinue two elements of the General Research Support Grant Program in order to retain an acceptable level of the more program-oriented research project grants administered and funded by the separate research institutes.

2. National Library of Medicine: The requested net increase of $1.5 million will permit operations to continue at about the same level as 1974 with some increase in the following areas:

   a. Research grants.

   b. Additional support for the development of experimental communications systems at the Lister Hill National Center for Biomedical Communications.

   c. Expansion of the MEDLARS data base.

   d. Updating of the bibliographic file of TOXLINE.

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(In thousands)

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Heart	287,927	286,749	309,299	+22,550
(Obligations)	(244,674)	(329,785)		(-20,486)
Dental	45,793	43,955	43,959	+4
(Obligations)	(40,439)	(49,309)		(-5,350)
Arthritis	158,257	153,136	152,961	-175
(Obligations)	(139,906)	(171,487)		(-18,526)
Neurology	124,469	119,993	119,958	-35
(Obligations)	(105,280)	(139,125)		(-19,167)
Allergy	107,698	110,461	110,404	-57
(Obligations)	(101,108)	(117,050)		(-6,646)
General Medical Sciences	173,757	166,805	168,329	+1,524
(Obligations)	(149,879)	(190,683)		(-22,354)
Child Health	126,002	124,950	124,897	-53
(Obligations)	(109,709)	(141,243)		(-16,346)
Eye	36,843	39,998	39,947	-51
(Obligations)	(33,832)	(42,993)		(-3,046)
Environmental Health	30,305	28,338	28,684	+346
(Obligations)	(25,854)	(32,702)		(-4,018)
Research Resources	135,785	126,935	82,700	-44,235
(Obligations)	(98,964)	(163,707)		(-81,007)
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(Obligations)	(3,852)	(5,529)		(-745)
Total Research	1,716,710	1,733,481	1,785,922	+52,441
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Library	28,413	26,254	27,738	+1,484
(Obligations)	(24,809)	(29,775)		(-2,037)
Buildings & Facilities	8,500	8,000	3,000	-5,000
(Obligations)	(3,394)	(15,462)	(9,791)	(-5,671)
Office of the Director	12,785	12,993	18,124	+5,131
(Obligations)	(12,243)	(12,993)		(+5,131)
TOTAL NIH BUDGET AUTHORITY	1,766,408	1,780,728 1/	1,834,784	+54,056
(Obligations)	(1,518,944)	(2,030,315) 1/		(-188,740)

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Interior	23	35	33	33	0	0
Transportation**	42	39	65	65	0	0
AEC	105	103	111	119	8	7
Environ. Protection	13	15	20	21	1	5
NASA	75	50	42	62	20	48
NSF	34	37	45	46	1	2
VA	63	69	74	85	11	15
Other	20	22	37	37	0	0

*Covers medical and health-related R & D (projects, resources, and general support) but not training or construction. Details may not add to totals because of rounding.

**Data since 1973 are not strictly comparable with those for prior years, as coverage has been improved.

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RESEARCH TRAINING AND HUMAN EXPERIMENTATION (H.R.5640, H.R.7724, S.2071 S.2072)	9/11/73--Passed H.R.7724 amended.	5/31/73--Passed H.R.7724 amended. Hearings held on 9/27 & 28/73 prior to conference (H.R.10403).
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NATIONAL INSTITUTE OF HEALTH CARE DELIVERY (S.723,H.R.6582)	5/15/73--Passed S.723 amended.	
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FEDERAL FIRE PREVENTION & CONTROL ACT (BURN RESEARCH) (S.1769, H.R.8329)	11/2/73--Passed S.1769 amended.	2/7/74--H.Rept.93-795 (H.R.11989).
HEMOPHILIA ACT OF 1973 (S.1326, H.R.11479)	Hearings began 11/15/73.	
MEDICAL DEVICE SAFETY ACT (S.2368, H.R.9984)	2/1/74--Passed S.2368 amended.	Hearings began 5/30/73.
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TAB 7

BACKGROUND INFORMATION ON THE ORGANIZATION AND BUDGET OF THE NATIONAL INSTITUTES OF HEALTH [1]

Robert S. Stone, M.D.[2]

		Page
I.	Organization of the National Institutes of Health	1
II.	The Current Year (Fiscal 1974) Budget	3
III.	1975 Budget Authority	3
IV.	Federal Budgets for Medical R&D, FY 1971-74	6
V.	Legislation and Pending Bills	7

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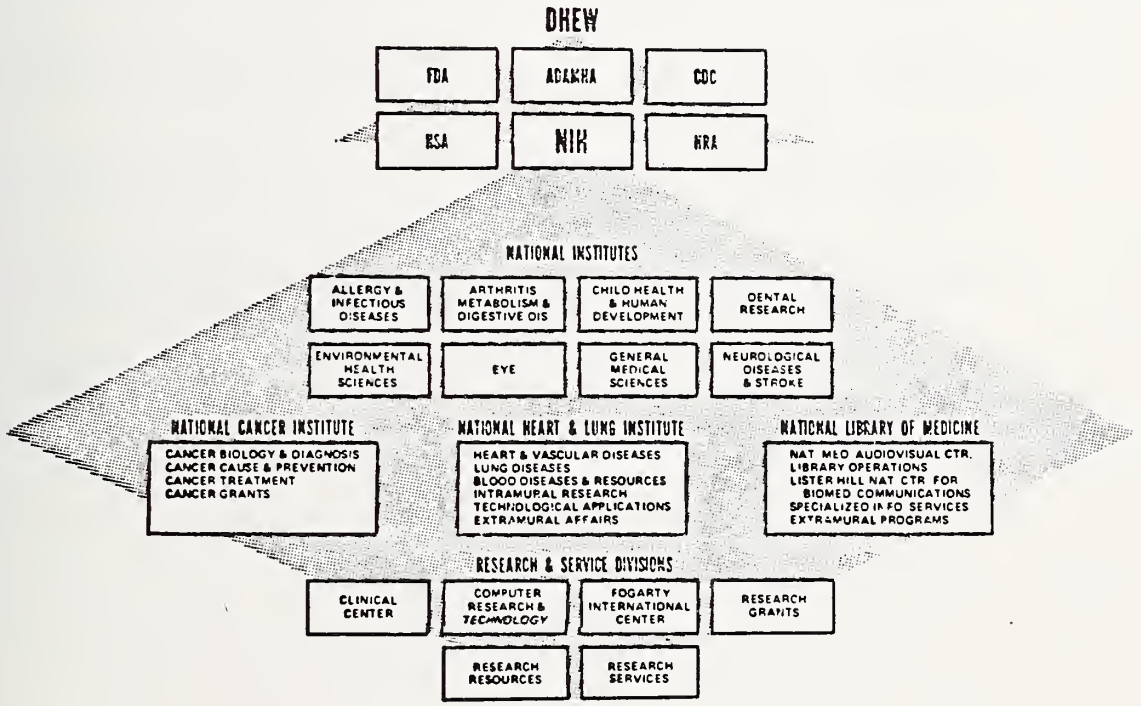
1 Prepared for presentation at the Annual Meeting of the Association of Professors of Medicine, Atlantic City, N.J., May 4, 1974.

2 Director, National Institutes of Health, Public Health Service, U.S. Department of Health, Education, and Welfare.

I. ORGANIZATION OF THE NATIONAL INSTITUTES OF HEALTH



Principal Officers, National Institutes of Health:

Director	Dr. Robert S. Stone
Deputy Director	(vacant)
Deputy Director for Science	Dr. DeWitt Stetten, Jr.
Assistant Director for Intramural Affairs	Dr. Philip S. Chen, Jr.
Associate Director for Collaborative Research	Dr. Leon Jacobs
Associate Director for Extramural Research and Training	Dr. Thomas E. Malone
Associate Director for Program Planning and Evaluation	Dr. Thomas J. Kennedy, Jr.
Associate Director for Clinical Care	Dr. Robert S. Gordon
Associate Director for Administration	Mr. Leon M. Schwartz
Associate Director for Communications	Mr. Storm Whaley

The 1974 Labor-HEW Appropriation Act (Public Law 93-192, dated December 18, 1973) provides $1,859,771,000 for the National Institutes of Health (NIH). The Act also includes a proviso which permits the Administration to allocate up to 5% less than the amounts appropriated for DHEW. As a result of this provision the NIH has been apportioned $1,784,845,000, or a reduction of about 4.8%, from its 1974 appropriations. In addition to the above, 1973 impounded funds totalling more than $239 million have been released for obligation in fiscal year 1974.

The tables that follow show: (a) the 1975 budget as compared with the 1974 budget authority, and (b) an appropriation summary for fiscal years 1973 through 1975. The amounts for budget authority in 1973 and 1974 may deviate slightly from actual figures since they have been made comparable to the 1975 estimate.

III. 1975 BUDGET AUTHORITY
(In thousands of dollars)

	1974	1975 Request	Change over 1974
Research Institutes & Divisions			
Research grants	$974,825	$987,544	+$12,719
Training programs	137,040	122,270	-14,770
Laboratory and clinical research	155,618	165,257	+9,639
Research and development contracts	295,987	325,821	+29,834
Other direct operations	108,406	117,932	+9,526
Cancer control program	34,055	45,098	+11,043
Cancer construction	27,550	22,000	-5,550
Subtotal, Institutes & Divisions	1,733,481	1,785,922	+52,441
National Library of Medicine	26,254	27,738	+1,484
Other	20,993	21,124	+131
Total, NIH	1,780,728[1/]	1,834,784[1/]	+54,056

1/ Includes Cancer Research Initiative of $527,399,000 in 1974 and $600,000,000 in 1975.

Highlights of the 1975 Budget

The President's 1975 budget for NIH provides an overall net increase of $54 million.

1. Research: The request represents a net increase over 1974 of $52.4 million. The major features of the budget for research are:

   a. An increase of $72.6 million in cancer research for the continuation and expansion of the cancer research initiative in accordance with the National Cancer Program Plan.

   b. An increase of $22.6 million in heart and lung research including $7.6 million for heart and vascular diseases; $7.4 million for lung disease and $5.3 million for blood diseases and resources.

   c. A decrease of $45.2 million representing the decision to discontinue two elements of the General Research Support Grant Program in order to retain an acceptable level of the more program-oriented research project grants administered and funded by the separate research institutes.

2. National Library of Medicine: The requested net increase of $1.5 million will permit operations to continue at about the same level as 1974 with some increase in the following areas:

   a. Research grants.

   b. Additional support for the development of experimental communications systems at the Lister Hill National Center for Biomedical Communications.

   c. Expansion of the MEDLARS data base.

   d. Updating of the bibliographic file of TOXLINE.

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TAB 2

#725

MECHANISMS FOR SUPPORT*
(Outline)

Robert S. Stone, M.D.**

I. In preface to comments on support mechanisms used in NIH programs, I'd like to run through a few slides placing NIH in the context of total national and Federal expenditures for biomedical R & D.

A. SLIDE 1: Medical R & D as a Proportion of Total Health Cost, 1960 and 1973 Est.

1. As the Nation's total expenditure for health--doctors, hospitals, drugs, research, insurance, etc.--has increased since 1960, medical R & D has increased faster.

2. It has risen from about $845 million to $3.5 billion, or from 3% to 4% of the total health cost, now estimated at $94 billion.

3. Over this period the Federal support of medical research has risen from 1 7% of the total health cost to about 2.4%.

4. This is a relatively modest investment in "product improvement." That is, research is a small fraction of the cash flow of the health industry.

B. SLIDE 2: Medical R & D as a Proportion of Total R & D Cost, U.S. 1960 and 1973 Est.

1. As U.S. medical and health-related research grew from about $845 million in 1960 to $3.5 billion in 1973, it doubled as a proportion of all R & D, rising from 6 to 12 percent. (Bulk of R & D is national defense program.)

2. The two coins show where the $3.5 billion comes from and where it is spent. The Government, contributing nearly two thirds of all the funds, performs only a sixth of the research.

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*Prepared for use at the Annual Meeting of the American Society for Microbiology, Chicago, Ill., May 14, 1974.

**Director, National Institutes of Health, U.S. Dept. of Health, Education, and Welfare.

C. SLIDE 3: Federal Health Expenditures, FY 1966-75 Est.

1. This shows R & D in the context of all Federal health expenditures. Over a decade it has risen from $1.1 billion to $2.6 billion--that is, it has more than doubled.

2. Total Federal health costs, however, have mounted by 6-fold, due largely to Medicare and Medicaid.

3. The red line represents the growth of the total in constant dollars, or as though there had been no inflation in terms of GNP.

D. SLIDE 4: Funds for Medical R & D by Source, U.S., 1961-73 Est.

1. Here the universe is total medical R & D. The Federal emerges as a major share, fairly constant for the past decade.

2. In 1973 Federal support will be about $2.2 billion against non-Federal $1.3 billion, totaling $3.5 billion.

3. Note that the private share continues to rise despite taxpayers' support through government. May be mutually stimulating.

4. "Other non-Federal" refers to private foundations, health agencies, other private sources, and State and local governments.

E. SLIDE 5: NIH Funds as a Proportion of Nation's Medical R & D, Est. 1973 and 1974

1. Recent estimates of medical R & D support for the Nation are $3.5 billion for 1973 and $4.1 billion for 1974.

2. In fiscal 1973, NIH R & D obligations totaled $1.3 billion. This is expected to rise to $1.7 billion in 1974, largely through release of funds withheld last year.

3. Industry will rise slightly, from $1.0 to $1.1 and drop from 29 to 27 as a percent of the total.

4. Other non-Federal will remain about the same.

F. SLIDE 6: NIH in Fiscal Year 1973 Accounted for--

1. 8% of all Federal R & D; 40% of Federal funds for R & D at educational institutions; 37% of Federal funds for academic science (defined as R & D, training, facilities, and resources).

2. Shows the relative importance of NIH among Federal agencies, particularly with respect to higher education. Compare the 8% of all Federal R & D with the 40% of R & D in schools.

3. Although NIH is not a major Federal supporter of research, it is the major Federal supporter of research in academic institutions. In schools of medicine, it is an even more significant contributor.

4. DHEW accounts for about half of Federal support of academic science; NSF plus DHEW, for about two-thirds.

II. We may now consider the programs and instruments by which NIH awards its supportive research funds.

A. SLIDE 7: NIH Obligated Funds by Function, FY 1955-74.

1. The chart affords a historical view of all NIH funding except that for programs no longer with NIH--the National Institute of Mental Health, Division of Biologics Standards, Bureau of Health Manpower Education, and others.

2. The fiscal 1974 estimate is represented by two bars--the funds withheld in '73 and released for use this year, and the current appropriation.

3. NIH functions include both the support of research and the development of biomedical scientists and institutions.

4. "Research," about 80% of the program, includes direct and collaborative activities, regular grants, general research support grants, and special grants (program projects and centers).

5. Total grants comprised 66% of all NIH funds in '73; will account for 64% in '74. R & D contracts (mostly in collaborative programs) accounted for 17% of all NIH funds in '73 and will rise to 17.5% this year. "Research construction grants," once a $100 million program, now includes only cancer construction--$34 million in FY '74.

6. There will not be time to discuss the general research support program--the formula grants to institutions--which this year represent only 5 or 6 percent of the research award money, and drop to about a tenth of that in the 1975 President's Budget.

B. SLIDE 8: NIH Funds Obligated for R & D, FY 1955-73.

1. This chart permits comparison of growth in NIH grants and contracts.

2. It represents the R & D obligations of NIH on a log scale over time. "Total R & D" includes all R & D programs. Three of these are represented by the other curves--R & D grants, labs & clinics, R & D contracts.

3. The sharp change in R & D grants between FY 1956 and '57 reflects an increase of more than 75 percent--as revealed in the inset. Labs & clinics--the intramural research program--has enjoyed a gradual rise and much stability. R & D contracts is the fastest growing program.

4. For FY 1973 R & D grants totaled $815 million, R & D contracts $252 million.

C. SLIDE 9: NIH Extramural Research Program Awards and Their Percent Distribution, FY 1967-74 Est.

1. This gives a more detailed view of trends in extramural support over time, showing all research programs--general research support grants, R & D contracts, special grants, and traditional grants.

2. The overall program has almost doubled since fiscal 1967.

3. The principal increases are in contracts and large grants, which together have more than doubled.

4. Research projects have grown somewhat, but in relative terms--as seen in the percentage distribution--they have considerably diminished.

5. This, as you know, has been a matter of concern in the scientific community, and we have given serious attention to the causes and implications.

D. SLIDE 10: NIH Extramural Research Program Awards by Grouped Institutes, FY 1967-74 Est.

1. The trend toward contracts and larger grants--that is, program projects and centers--is strongest in three institutes: National Cancer Institute, Heart and Lung, and Child Health and Human Development.

2. These institutes are changing the way they do business.

3. The other institutes and research divisions continue to operate in the traditional way.

E. SLIDE 11: Percentage Distribution of NIH Extramural Research Program Awards by Grouped Institutes, FY 1967-74 Est.

1. The same data distributed by percent reveal the striking proportional decrease in traditional grants for the three unusual institutes and the fairly steady state for the rest of the NIH research support program.

F. SLIDE 12: Extramural Research Program Awards for Three NIH Institutes, FY 1967 and 1974 Est.

1. Here the panels of the previous chart have been separated by institute, showing absolute and proportional data at two points of time.

2. In each case, the percentage of funds spent for such grants has dropped considerably.

G. SLIDE 13: Relative NIH Research-Grant and Contract Support Among Top 10 Grantee Institutions, FY 1973.

1. We wanted to see how grantee institutions varied in their use of these instruments.

2. Among the top 10 grantee institutions in terms of total NIH research support, there are some interesting variations.

a. Harvard, Hopkins, U.C.L.A., Stanford and Yale show a preference for traditional project grants over large grants in terms of aggregate funding.

b. Columbia and the State universities--Washington, Wisconsin, U.C.S.F., and Pennsylvania--lean toward large grants.

c. In all these institutions, however, large grants figure prominently as a source of funds.

H. SLIDE 14: Relative NIH Research-Grant and Contract Support Among 10 Selected Universities Receiving $6-10 Million, FY 1973.

1. The total volume of support to the institution tends to correlate strongly with the use of large grants.

2. These institutions, intermediate in terms of total NIH support, are receiving more of their funds in small, individual grants than the top 10.

I. SLIDE 15: Relative NIH Research-Grant and Contract Support Among 10 Selected Universities Receiving $1-3.5 Million, FY 1973.

1. These small institutions--like the smaller institutes of NIH--are doing most of their research in the traditional manner.

2. There are many ways to interpret the data.

   a. One is simply to say that large grants make for large aggregate support.

   b. A more penetrating interpretation might be that institutions providing a full research program--a highly developed research environment--are better prepared to command and sustain program project and center grants.

J. SLIDE 16: NIH Budget Authority, FY 1973-75, By Program.

1. Before leaving the subject of mechanisms of support in quantitative terms, we should take a look at the current budget picture.

2. Working back from FY 1975 President's Budget, comparable columns are shown for FY '74 and '73. [Comparable in that--

   a. Funds withheld in '73 and released for '74 are shown in the '73 column,

   b. Formula grants to institutions (GRS) are treated as though appropriated to DRR in '73 rather than drawn from institute funds,

   c. Other, lesser adjustments have been made.]

3. We see major increases over the 3 years for Cancer and Heart, a minor increase for Eye, a considerable drop for DRR. The other programs either decrease moderately or stay about the same.

4. From '73 to '75, total NIH funds increase $69 million, or 4%.

K. SLIDE 17: NIH Budget Authority by Mechanism, FY 1974-75.

1. Here the same budget for FY 1974 and '75 is arranged by mechanism of support.

2. We see major decreases for General Research Support grants (86%)--an *endangered* species--and for Research Training Grants (37%). There is some drop in Cancer Construction (20%).

3. Major increases are planned for Other Research Grants (mostly program projects, centers, and resources grants) (15%), R & D Contracts (10%), Fellowships (53%), and Cancer Control (32%).

4. The other changes are all minor increases.

5. There is a 3% increase in the total. [Lights.]

III. Evolution of the R & D grant and contract programs. The growth of the NIH grant and contract programs has been described. This has been accompanied by development of policies, procedures, and structure for administering the programs and awarding the funds.

A. Research grants, authorized by the National Cancer Act of 1937, were first reviewed by a National Advisory Council and awarded in November of that year.

1. The Act gave the Institute power to award grants for research projects with the approval of the Council, whose composition, term of office, rotation, and authority were specified.

2. Only ten grants were recommended that first year. Total funds awarded were just under $91,000. The largest grant went to E. O. Lawrence of the University of California to support the development of the cyclotron for clinical research on therapeutic uses of neutron rays and artificial radioactive substances.

3. In 1944 the codification of the laws under which the Public Health Service operated resulted in the enactment of Public Law 410, the Public Health Service Act. The law extended the NIH authority to award funds for research and research training to health problems generally.

4. With the termination of the wartime Office of Scientific Research and Development (OSRD), arrangements were made for the transfer of the remaining university contracts in the

biomedical area to NIH. These contracts, converted to grants, established NIH as the principal Federal agency supporting health-oriented research, basic and applied, in universities and other institutions.

5. In 1946 the Division of Research Grants was established to review and evaluate grant applications.

6. As each of the Institutes of NIH was created in subsequent years, the NCI prototype was repeated in an act authorizing grants-in-aid for research in non-Federal institutions when recommended by a National Advisory Council.

7. Meanwhile the Study Sections were organized under DRG to aid the Councils in reviewing grant applications for technical merit. These are composed predominantly of non-Federal scientists. They are discipline-oriented and serve all the Institutes and Councils.

8. Special review committees are also evolving to review applications when an appropriate Study Section is lacking.

9. Both types are now known as Initial Review Groups (IRGs).

B. The mechanism for awarding R & D contracts at NIH has not been as formal as that of grants.

1. Again it was the Cancer Institute that first used contracts extensively.

2. In 1957 the Cancer Chemotherapy Program got under way with its screening of drugs for anti-cancer activity.

3. It was 1961 before other Institutes--notably Heart, Allergy, Arthritis and Neurology--developed contract programs.

4. These were administered by the Collaborative R & D programs of the institutes, organized largely for the extension of "targeted" or "programmed" research in collaboration with non-Federal laboratories.

5. Although committees of experts were used from the start in reviewing contract proposals, the elaborate, orchestrated structure that had evolved around grants was not felt to be necessary.

6. This was largely because of the nature of the contract as an instrument implying staff control.

7. The trend today is toward more structured machinery for reviewing contracts, and peer review on a more formal basis is being instituted.

IV. SLIDE 18: Grant or Contract?--Criteria for Determing the Instrument of Choice.

A. Grant is appropriate for projects where--

1. The initial idea is conceived by the investigator; and

2. NIH supports or assists the conduct of research, development, or related activities directed toward NIH program goals; and

3. The performer defines details of the project and retains discretion and freedom of scientific and technical approaches toward project objectives from the outset; and

4. NIH maintains cognizance of progress to ensure that the project continues to be significant to the purposes and objectives of the award.

B. Contract is appropriate for projects where--

1. Initial idea is conceived or developed by NIH staff with advice of consultants; and

2. NIH procures a specific service or defined end product, including research, development, and related activities, for identified NIH program needs; and

3. NIH exercises direction or control under terms of the agreement by specifying the scope of the work and manner of performance, and

4. NIH must closely monitor technical and administrative performance to ensure that work on the project is accomplished in accordance with terms of the agreement.

C. Contract is mandatory in dealing with profit-making organizations.

V. SLIDE 19: Grants Vs. Contract: Type of Project Generally Supported.

A. Grants tend to be used for fundamental research, contracts for development.

B. Either may be appropriate for applied research.

C. Grants are used for institutional support and training.

D. Contracts, for multi-institutional clinical trials and the like under a common protocol.

E. Either, for the support of resources and facilities. For example--

1. Contracts for research reagents and testing services.

2. Grants for development of computer centers, animal colonies, and special laboratories.

VI. SLIDE 20: Grant Vs. Contract: Predominant Project Characteristics.

A. Projects under regular grants tend to be (or have) these characteristics: [see slide].

B. Projects under contracts: [see slide].

I. The next two slides illustrate the similarities and difference between grants and contracts.

A. SLIDE 21: Review Process for NIH Extramural Awards--Grants.

1. The black portions are the points in common.

2. Green indicates procedure applicable only to grants, though sometimes the difference is largely semantic--"application" vs. "proposal--or structural--" "Bureau/Institute/or Division" vs. "Division of Research Grants."

B. SLIDE 22: Review Process for NIH Extramural Awards--Contracts.

1. Here the procedure applicable to contracts is shown in red.

2. The part above the dotted line is unique to contracts, in that it represents the flow of ideas from NIH toward the investigator.

3. Below that point, there is little difference between this process and the previous one, except that the advisory structure is partly intramural.

4. The advisory groups range from ad hoc to chartered, from 5 or 6 members to about 2 dozen, and from all staff to all extramural--but care is exercised in maintaining expertise and objectivity as the proposal moves from intramural conception to contractor formulation and back for review and selection.

5. Later monitoring of performance is an active staff role.

VIII. To discern the direction of NIH administrative effort at this time in respect to support mechanisms, one might best review a recent recommendation by our Program Mechanisms Committee.

A. Last December a number of suggestions from both inside and outside NIH led my predecessor, Dr. Robert Marston, to appoint a committee of senior NIH staff to take a careful look at the development and administration of NIH programs.

B. SLIDE 23: Program Mechanisms Committee Recommendation 2.

1. Recommendation 2 of the committee states that there is need for NIH to "establish and refine the use of uniform policies and standard procedures by which its components define, develop, and implement programs, and initiate, review, select, and manage projects funded by contracts, grants, and other awards."

2. The proposal starts with the selection and development of programs, which speaks for more consistent use of the NIH advisory apparatus at this stage of the process.

3. It speaks further to the need for scientific and administrative analysis as the basis for all grant and contract awards, mentioning technical merit review by qualified peer groups as the key to objective evaluation.

4. Finally, the committee report expresses a need for improvements in the management of NIH programs and awards, with better definition of the roles and responsibilities of the personnel involved.

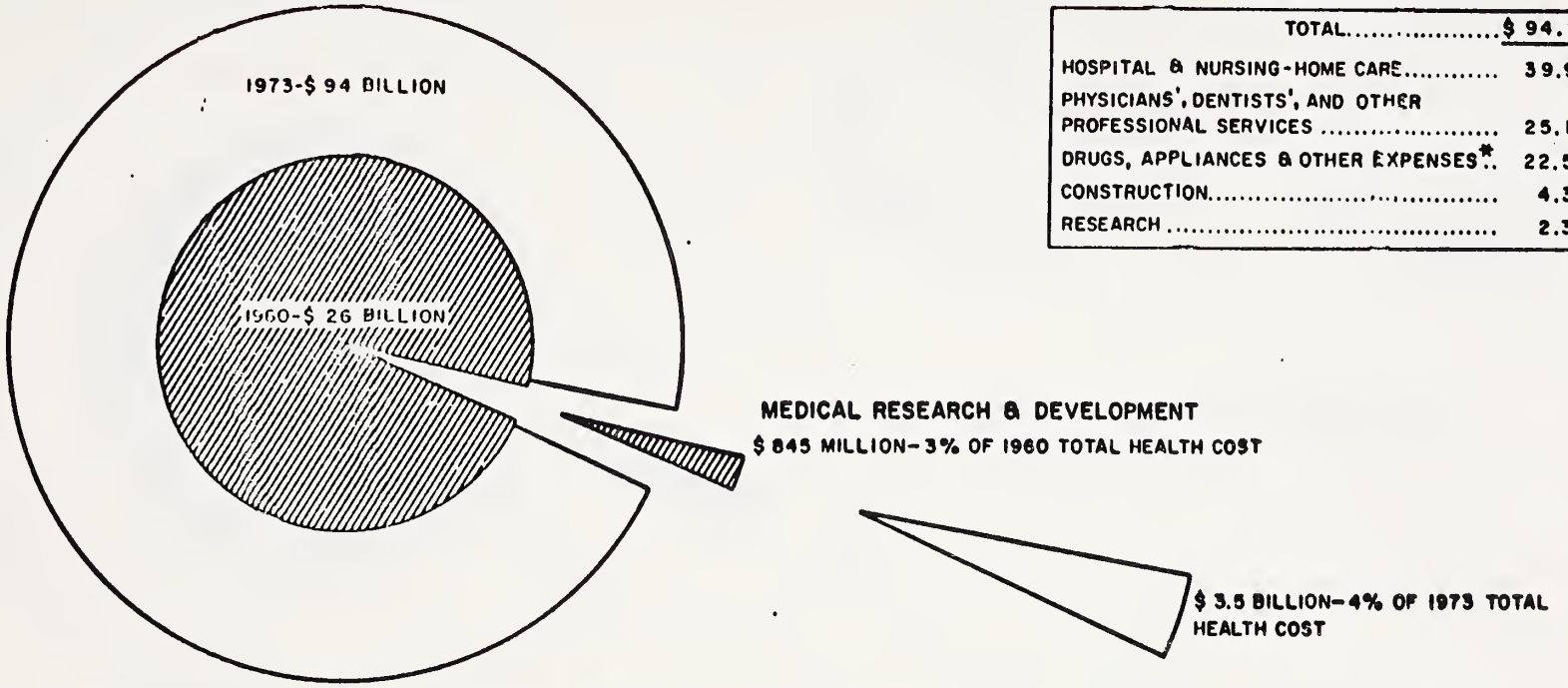
5. Staffs of the NIH Director and the Institutes are much involved these days in considering this recommendation, its implications, and steps toward its implementation.

6. Effective changes will come about only after thorough examination of present and proposed methods of operation, discussions of the advantages and disadvantages of each, and resolution of problems that might stand in the way of standardized procedures.

7. These steps are actively under way.

MEDICAL R & D AS A PROPORTION OF TOTAL HEALTH COST

UNITED STATES, 1960 AND 1973 EST.


TOTAL HEALTH COST
1973-$ 94 BILLION
1960-$ 26 BILLION
MEDICAL RESEARCH & DEVELOPMENT
$ 845 MILLION-3% OF 1960 TOTAL HEALTH COST
$ 3.5 BILLION-4% OF 1973 TOTAL HEALTH COST

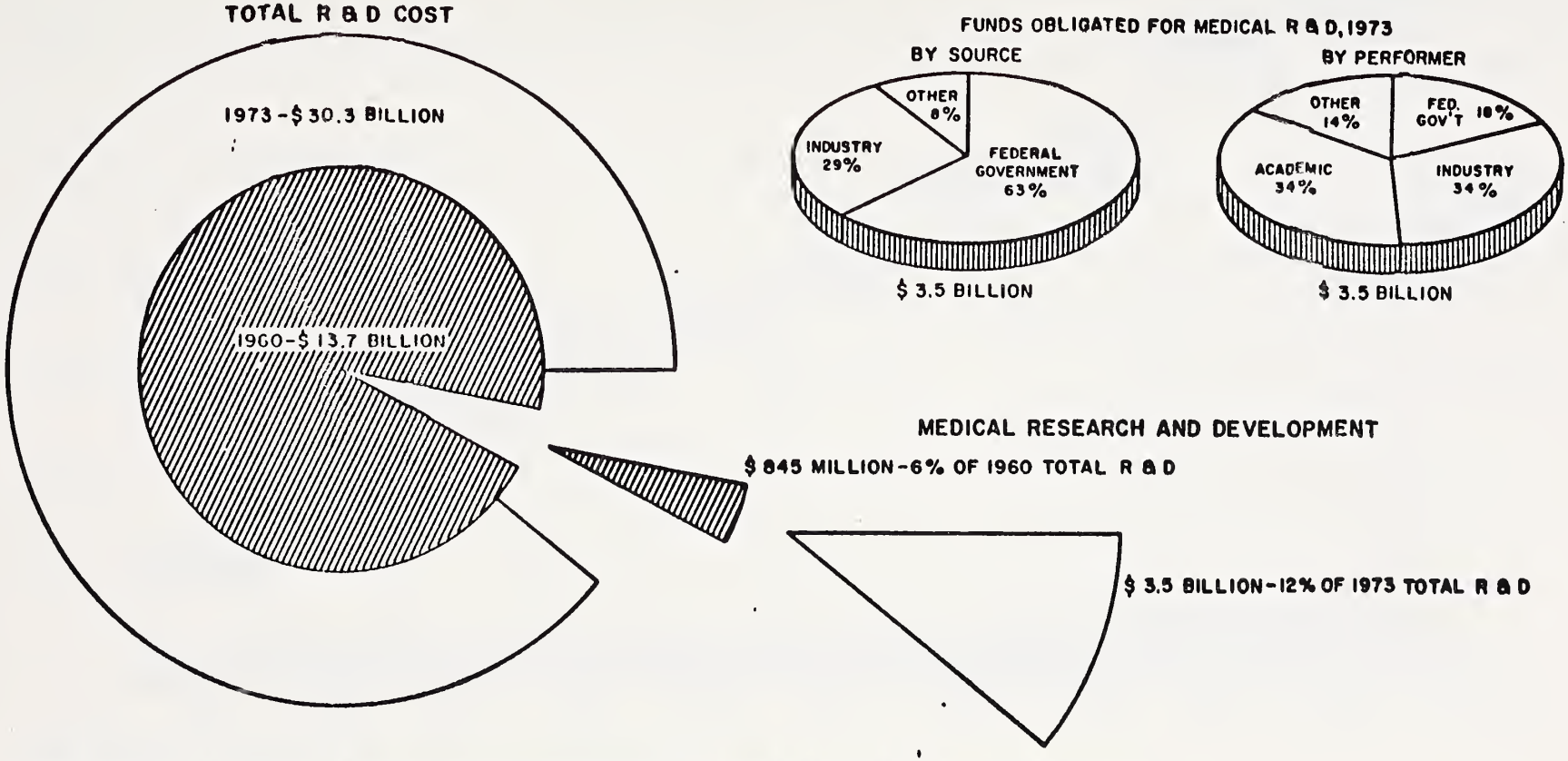
NATIONAL HEALTH COST, 1973
(IN BILLIONS)

TOTAL	$ 94.1
HOSPITAL & NURSING-HOME CARE	39.9
PHYSICIANS', DENTISTS', AND OTHER PROFESSIONAL SERVICES	25.1
DRUGS, APPLIANCES & OTHER EXPENSES*	22.5
CONSTRUCTION	4.3
RESEARCH	2.3

SOURCE FOR NATIONAL HEALTH COST: *SOCIAL SECURITY BULLETIN, VOL. 37, NO. 2, FEBRUARY 1974.*
FOR MEDICAL AND HEALTH-RELATED R & D: *NIH.*

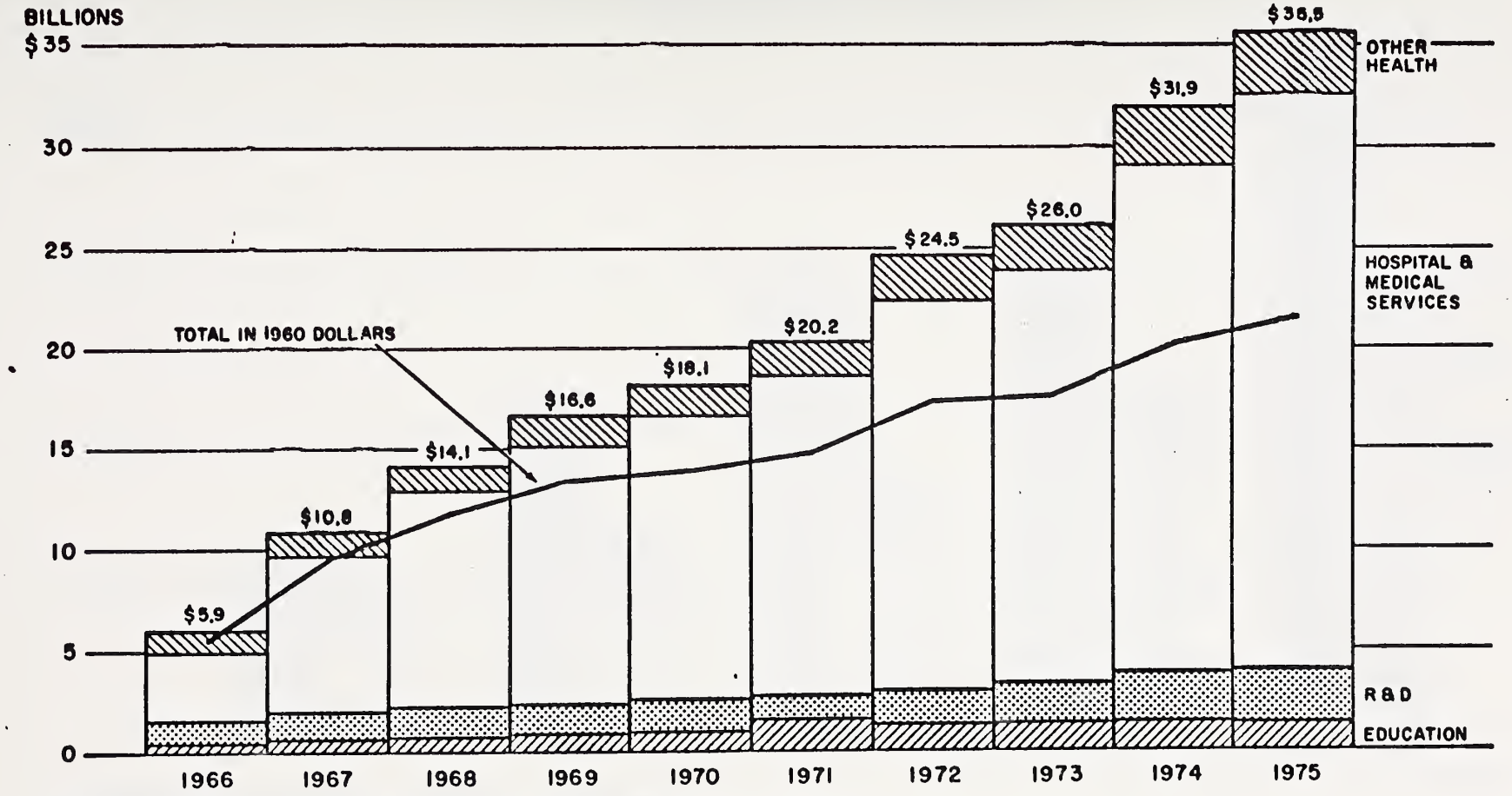
**INCLUDES INDUSTRY R & D.*

MEDICAL R & D AS A PROPORTION OF TOTAL R & D COST
UNITED STATES, 1960 AND 1973 EST.


TOTAL R & D COST
1973 - $ 30.3 BILLION
1960 - $ 13.7 BILLION
FUNDS OBLIGATED FOR MEDICAL R & D, 1973
BY SOURCE
OTHER 8%
INDUSTRY 29%
FEDERAL GOVERNMENT 63%
$ 3.5 BILLION
BY PERFORMER
OTHER 14%
FED. GOV'T 18%
ACADEMIC 34%
INDUSTRY 34%
$ 3.5 BILLION
MEDICAL RESEARCH AND DEVELOPMENT
$ 845 MILLION - 6% OF 1960 TOTAL R & D
$ 3.5 BILLION - 12% OF 1973 TOTAL R & D

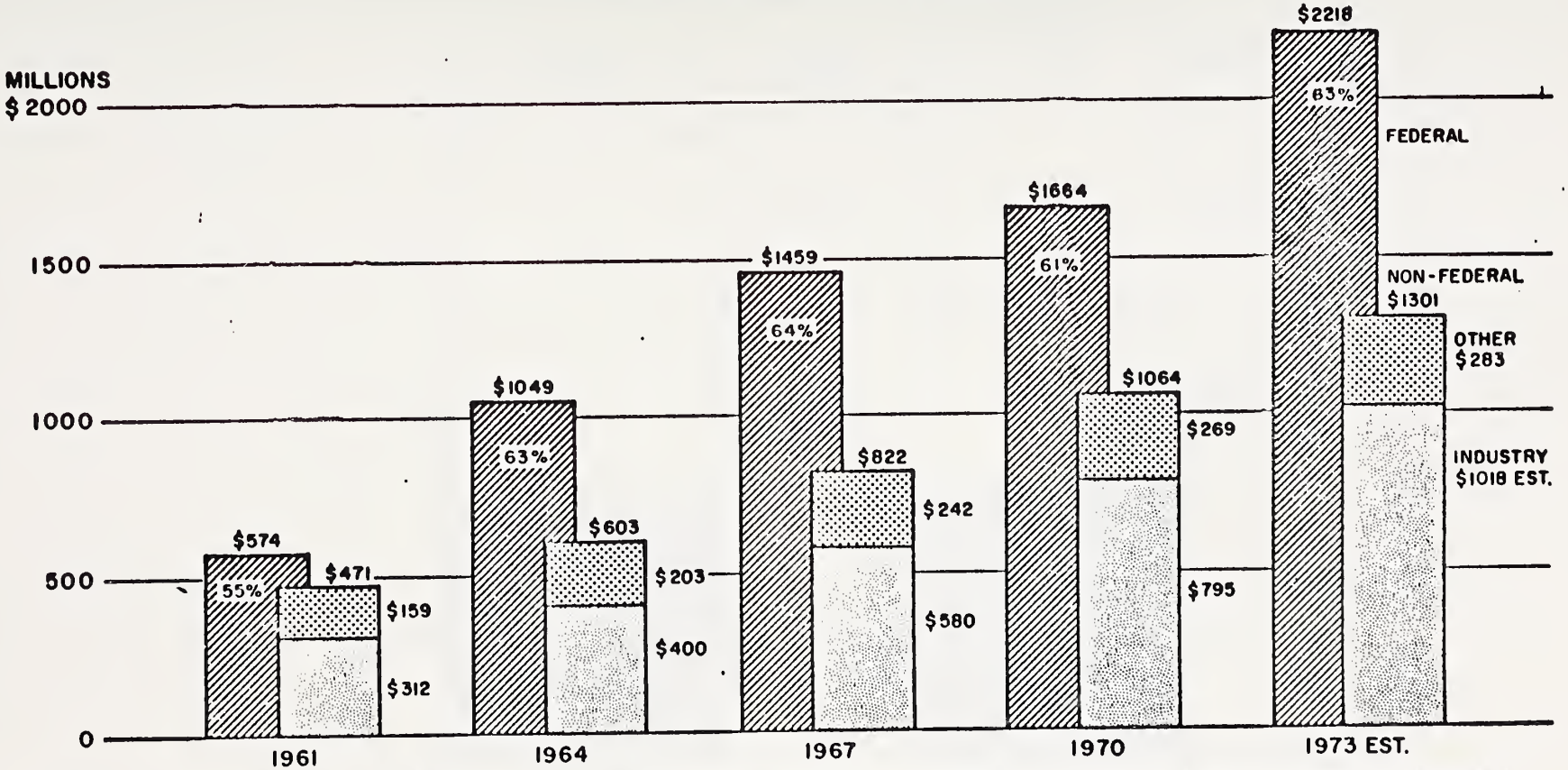
SOURCE FOR TOTAL R & D COST: *NATIONAL SCIENCE FOUNDATION.* FOR MEDICAL AND HEALTH-RELATED R & D: *NIH.*

FEDERAL HEALTH EXPENDITURES
FISCAL YEARS 1966 - 1975 EST.



SOURCE: *SPECIAL ANALYSIS, BUDGET OF THE U.S. GOVERNMENT*, 1967-1975 (annual).

FUNDS FOR MEDICAL R & D BY SOURCE*
UNITED STATES, 1961-1973 EST.

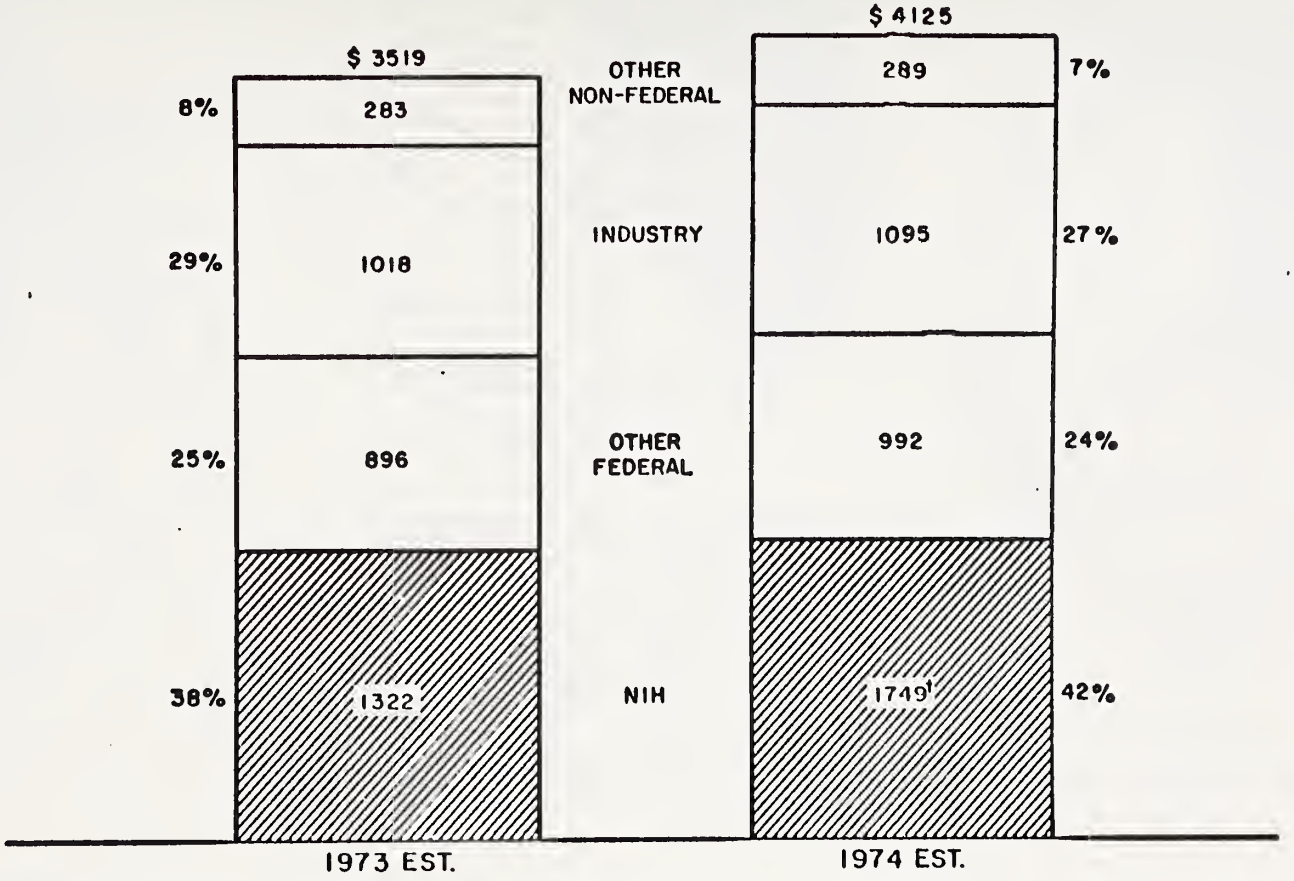


*COVERS ONLY MEDICAL AND HEALTH-RELATED R & D — NO TRAINING OR CONSTRUCTION. NON-FEDERAL DATA SINCE 1964 ARE NOT STRICTLY COMPARABLE WITH THOSE FOR PRIOR YEARS, AS COVERAGE HAS BEEN IMPROVED.

Slide 5

NIH FUNDS AS A PROPORTION OF NATION'S MEDICAL R & D*

EST. 1973 AND 1974 (IN MILLIONS)

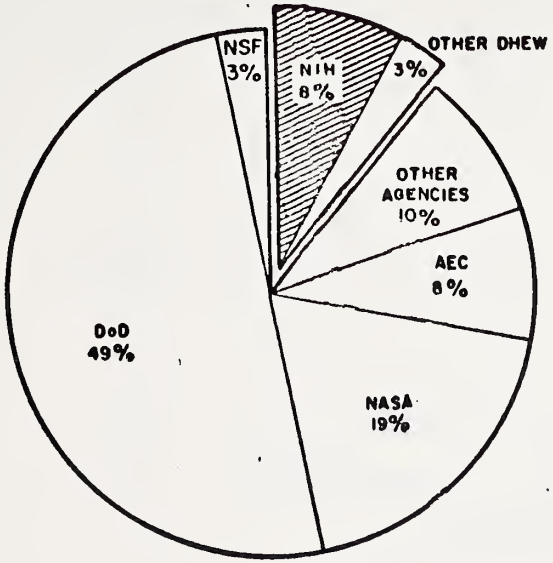


* COVERS ONLY MEDICAL AND HEALTH-RELATED R & D — NO TRAINING OR CONSTRUCTION.

† INCLUDES $162 MILLION WITHHELD IN FY 1973.

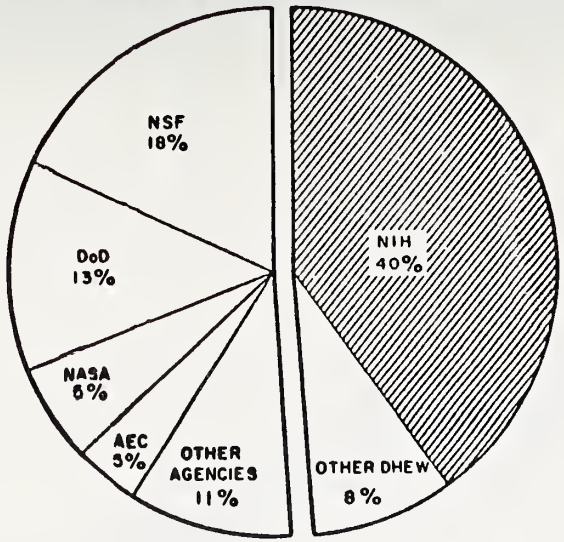
NIH ACCOUNTS FOR–

8% OF ALL FEDERAL R & D



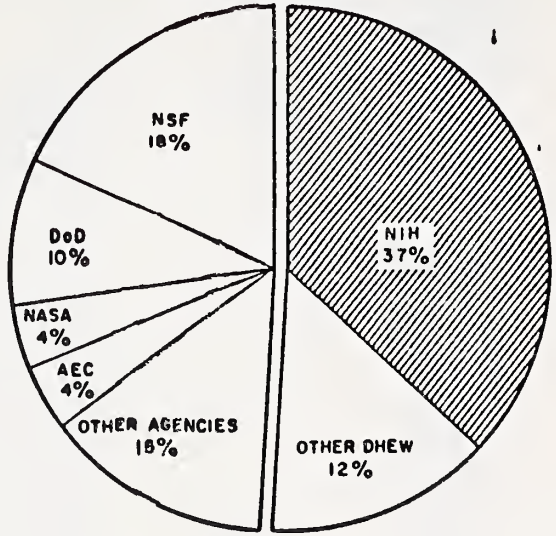
$17.0 BILLION

40% OF FEDERAL FUNDS FOR R & D AT EDUCATIONAL INSTITUTIONS



$1.9 BILLION

37% OF FEDERAL FUNDS FOR ACADEMIC SCIENCE†



$ 2.5 BILLION

FEDERAL SUPPORT, FY 1973 EST (IN MILLIONS)

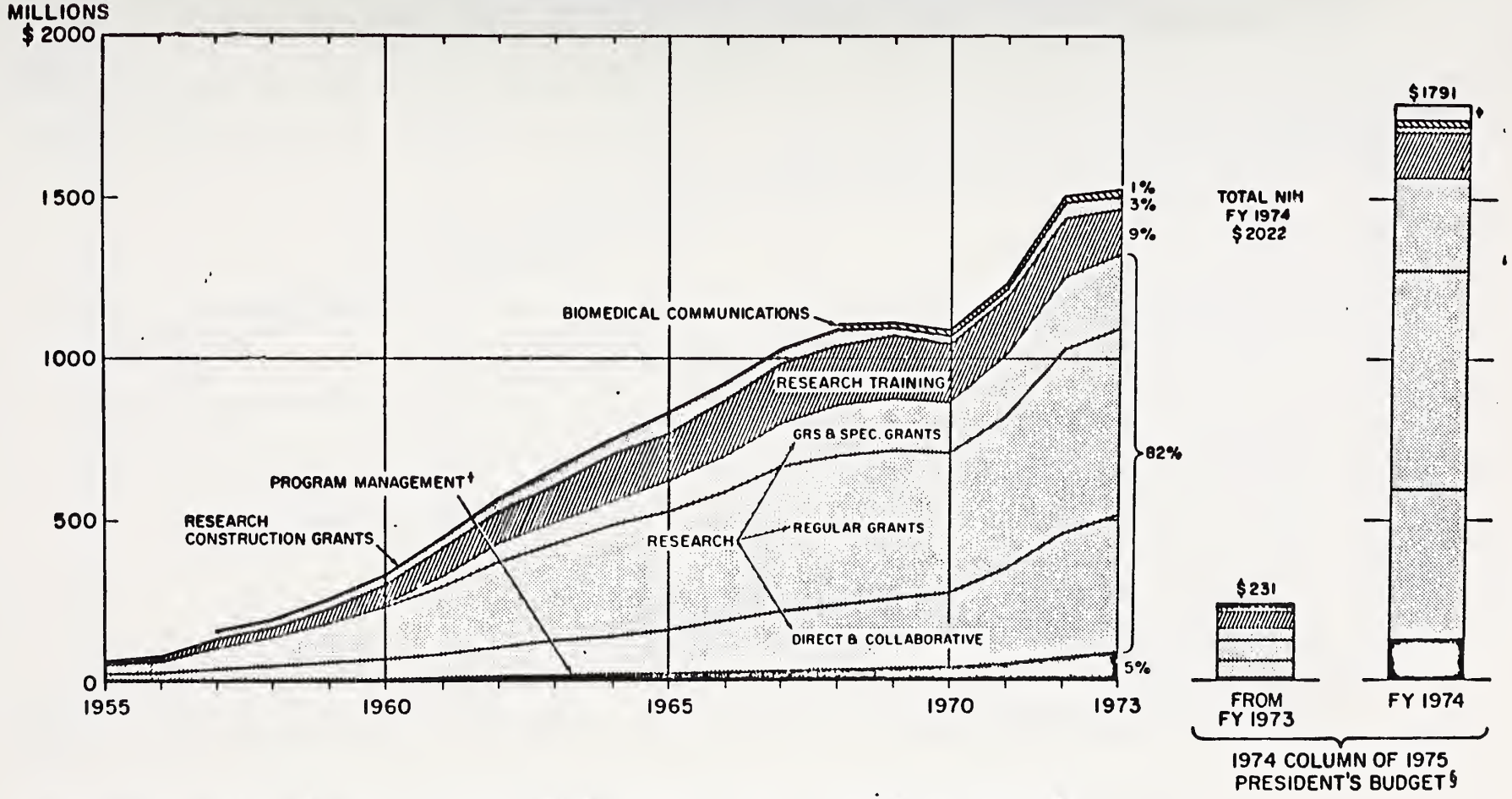
AGENCY	R & D	EDUC INSTITUTIONS*	
		R & D	ACADEMIC SCIENCE†
TOTAL	$ 16,976	$ 1,890	$ 2,521
DHEW	1,818	904	1,225
NIH	1,322	749	933
OTHER	496	155	292
NSF	462	340	450
DoD	8,362	255	255
NASA	3,200	103	111
AEC	1,358	87	96
OTHER	1,776	201	384

SOURCE: NSF AND NIH

*ESTIMATED. †R & D, TRAINING, FACILITIES, RESOURCES.

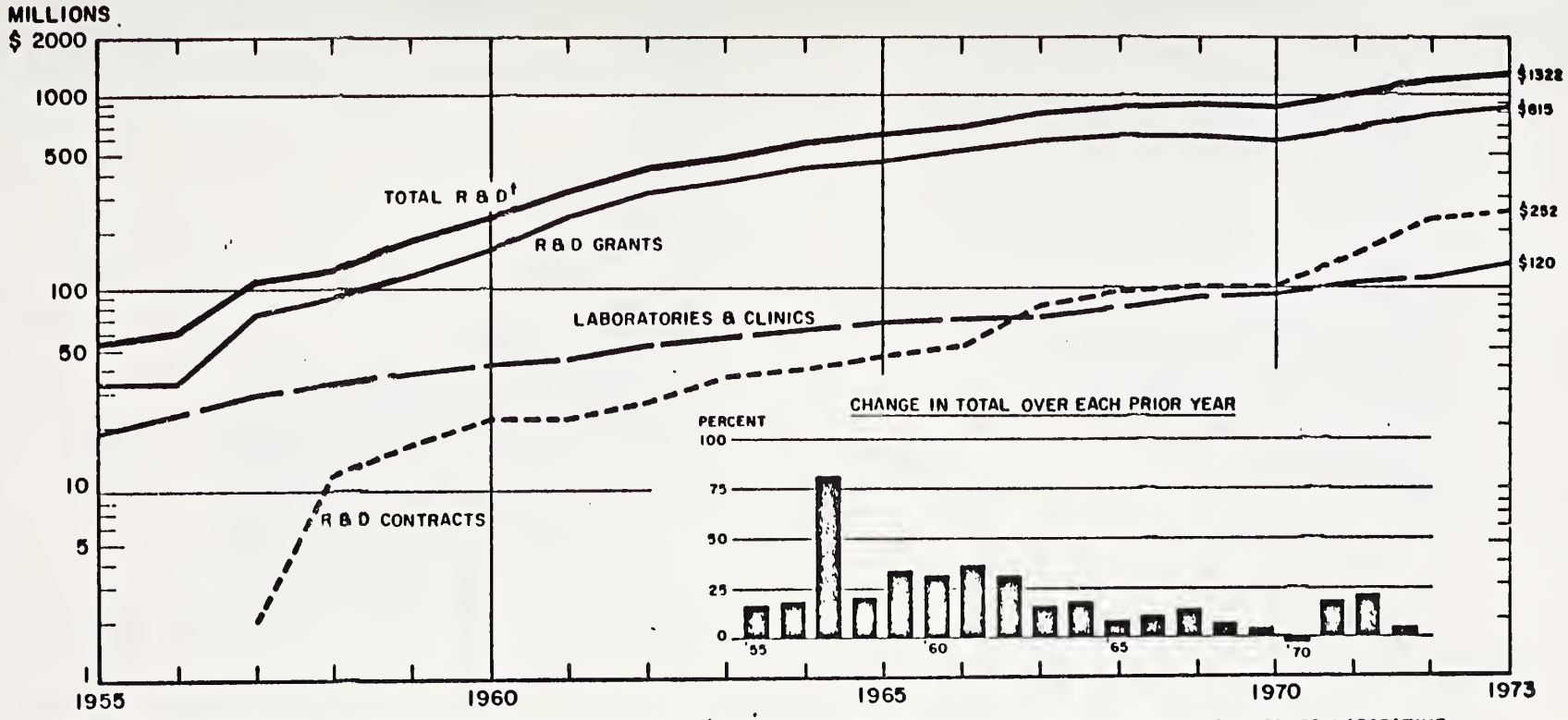
NIH OBLIGATED FUNDS BY FUNCTION, FY 1955-1974 EST.

EXCLUDING PROGRAMS THAT HAVE BEEN TRANSFERRED OUT *



* NIMH, COMMUNITY PROGRAMS, DBS AND BHME. ALSO EXCLUDES FOREIGN CURRENCY PROGRAM. INCLUDES NLM FROM FY 1968 ON.
† INCLUDES BUILDINGS AND FACILITIES FROM FY 1969 ON. BUT CHART EXCLUDES DIRECT CONSTRUCTION FOR PRIOR YEARS. ♦ CANCER CONTROL.
§ EXCLUDES NIMH SHARE OF GRS GRANTS, $8.0 MILLION.

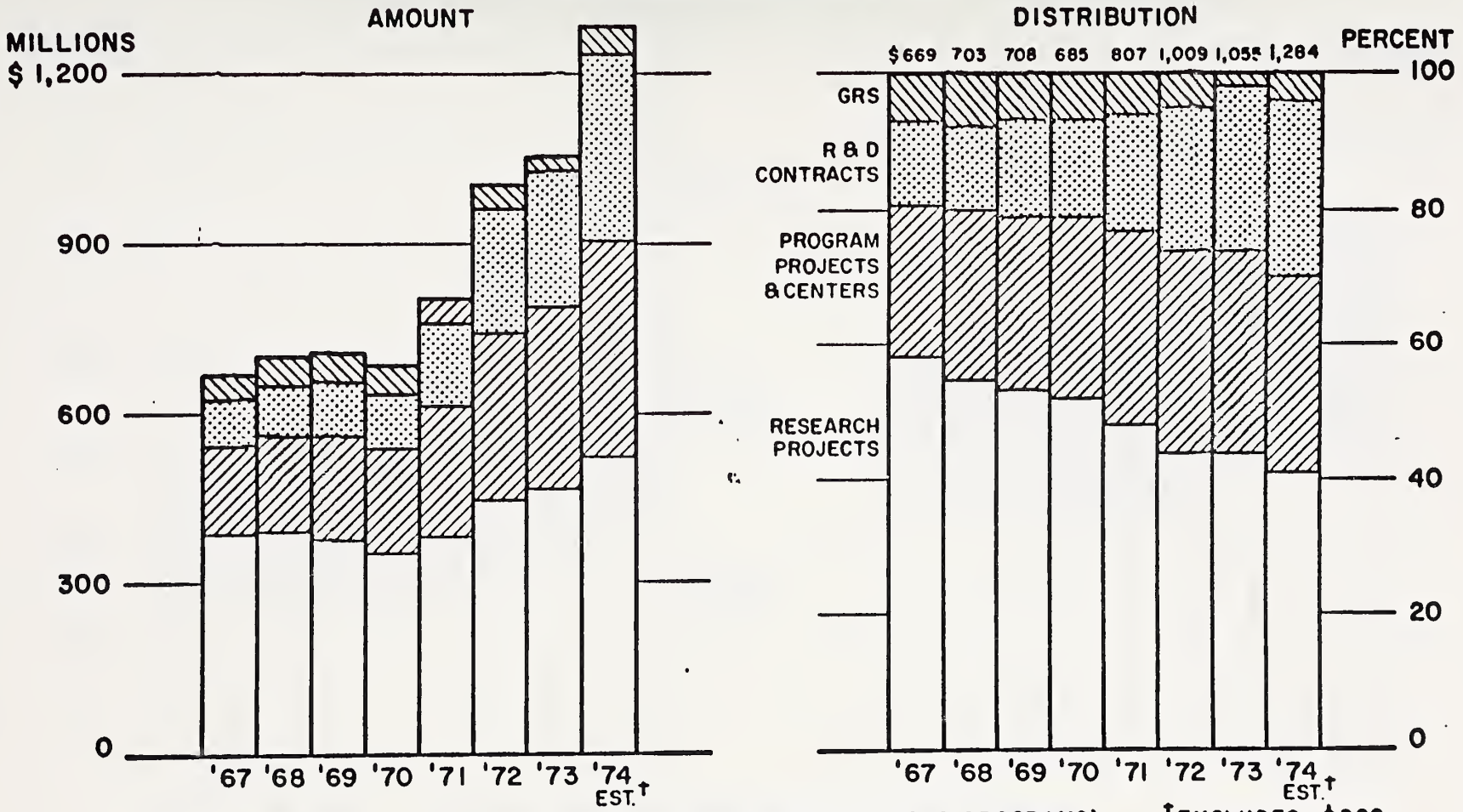
NIH FUNDS OBLIGATED FOR RESEARCH AND DEVELOPMENT, FISCAL YEARS 1955-1973*



*EXCLUDING CONSTRUCTION AND PROGRAMS TRANSFERRED OUT OF NIH. †R & D GRANTS, R & D CONTRACTS, LABORATORIES & CLINICS, COLLABORATIVE PROGRAMS, FIC, FOREIGN CURRENCY PROGRAMS, BIOMETRY/EPIDEMIOLOGY/FIELD STUDIES, AND PROGRAM MANAGEMENT APPLICABLE TO R & D.

NIH EXTRAMURAL RESEARCH PROGRAM AWARDS AND THEIR PERCENT DISTRIBUTION*

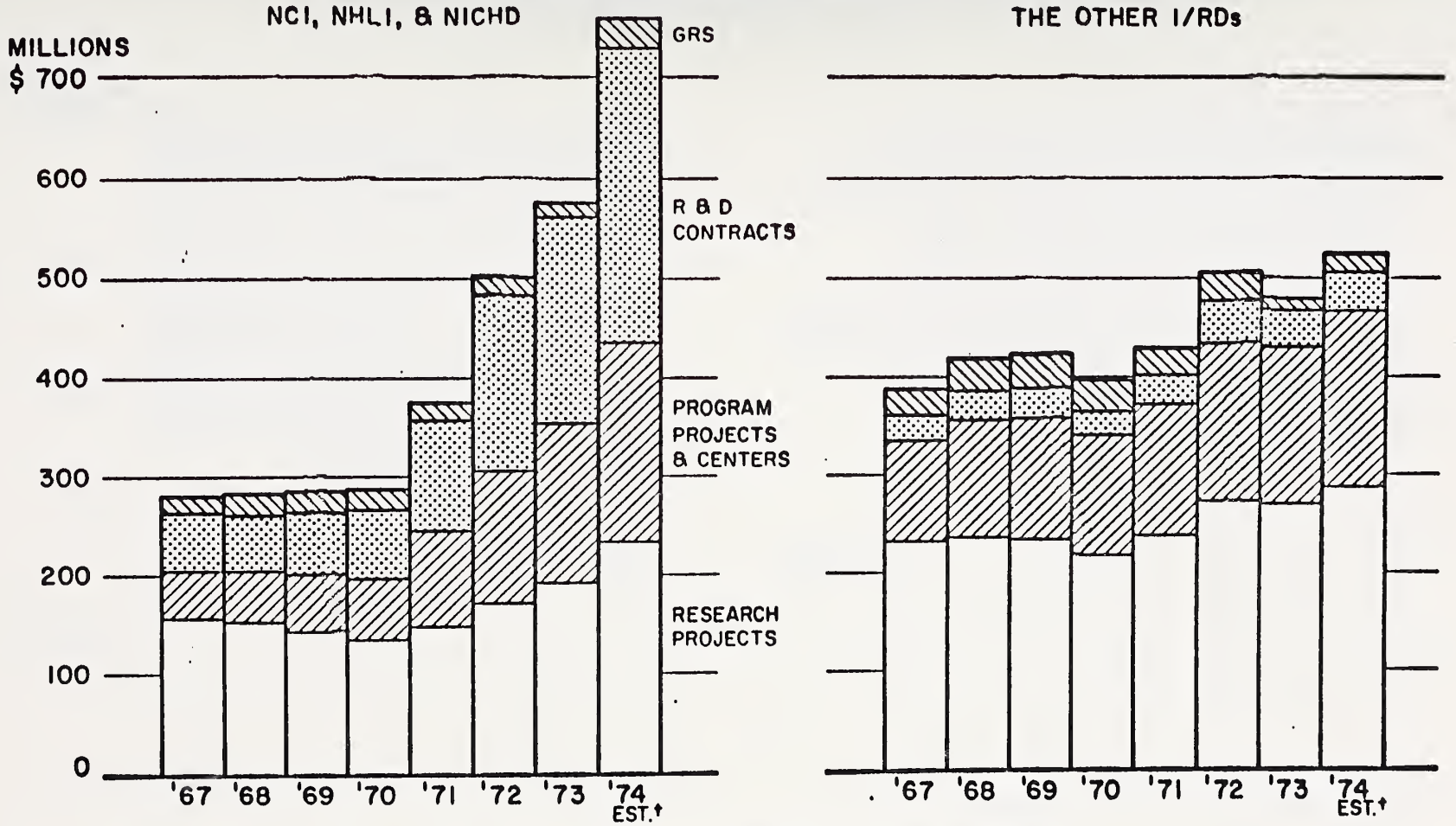
FISCAL YEARS 1967 – 1974 EST.



*INCLUDES I/RDs ONLY. EXCLUDES NIMH (AND NIMH PORTION OF GRS PROGRAMS). †EXCLUDES $228 MILLION WITHHELD IN FY 1973 AND RELEASED IN FY 1974.

NIH EXTRAMURAL RESEARCH PROGRAM AWARDS BY GROUPED INSTITUTES*

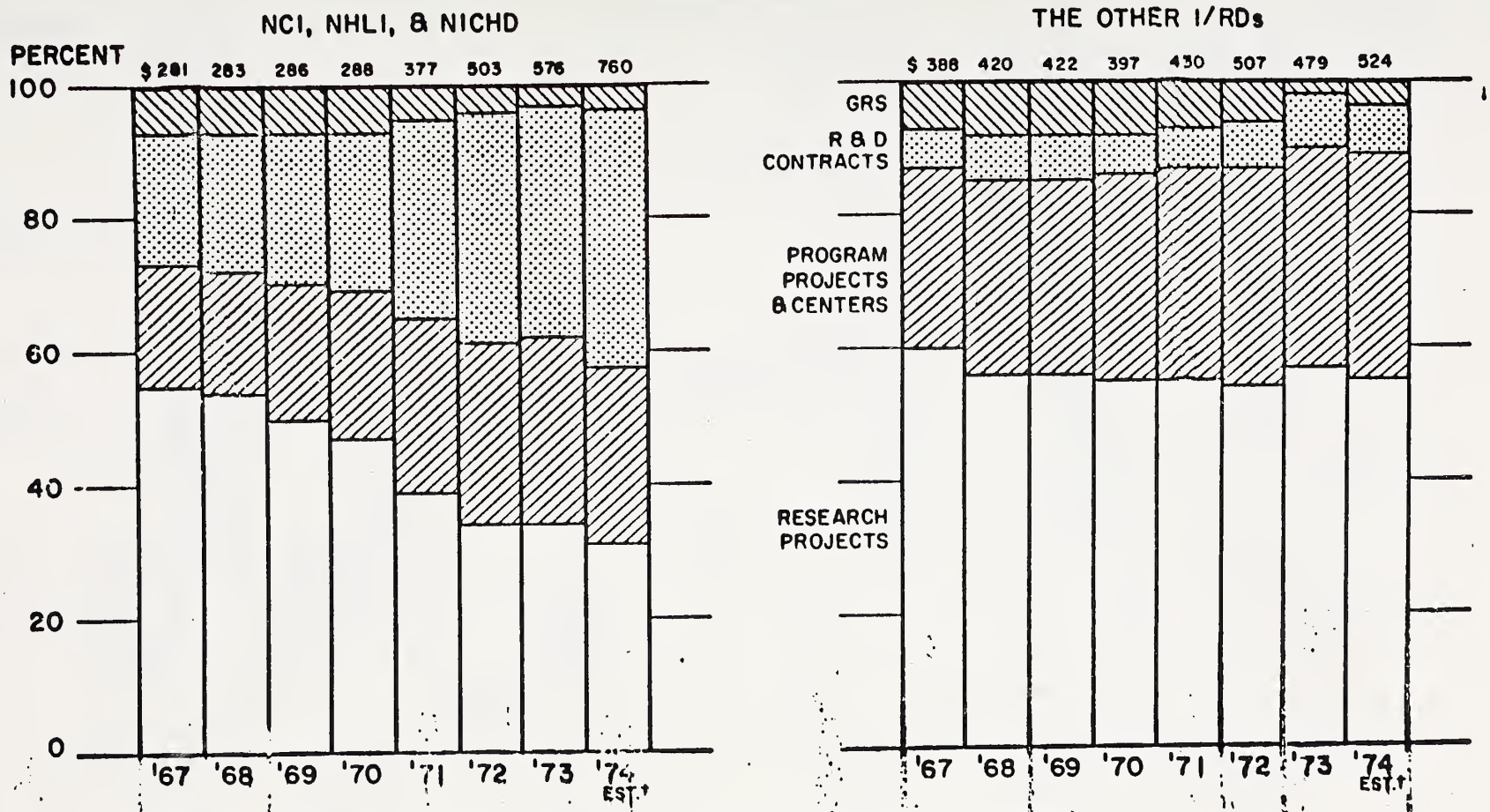
FISCAL YEARS 1967–1974 EST.



*INCLUDES I/RDs ONLY. EXCLUDES NIMH (AND NIMH PORTION OF GRS PROGRAM).
†EXCLUDES FUNDS WITHHELD IN FY 1973 AND RELEASED FOR USE IN FY 1974.

PERCENTAGE DISTRIBUTION OF NIH EXTRAMURAL RESEARCH PROGRAM AWARDS* BY GROUPED INSTITUTES, FISCAL YEARS 1967 - 1974 EST.

(DOLLARS IN MILLIONS)



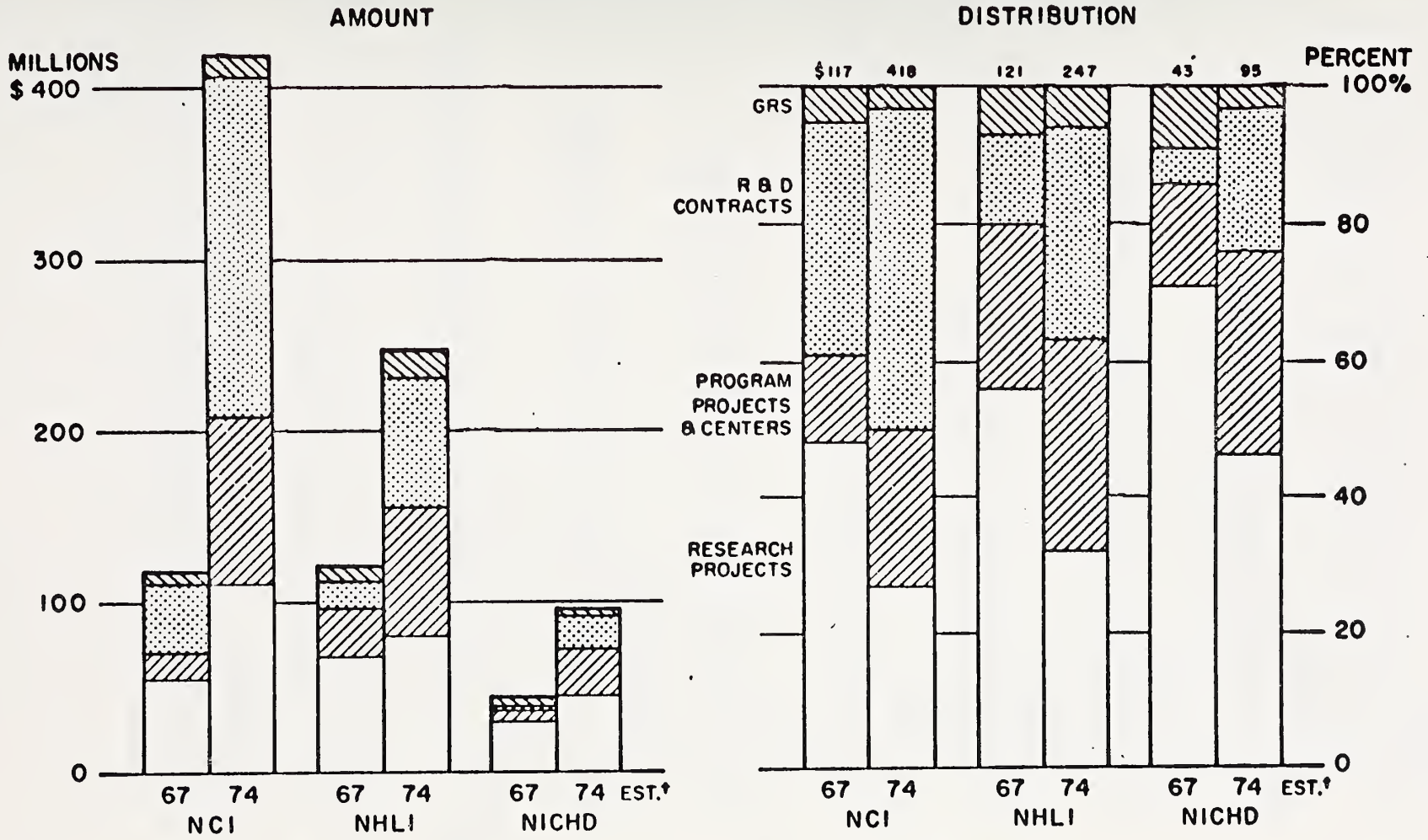
*INCLUDES I/RDs ONLY. EXCLUDES NIMH (AND NIMH PORTION OF GRS PROGRAM).

†EXCLUDES FUNDS WITHHELD IN FY 1973 AND RELEASED FOR USE IN FY 1974.

Slide 12

EXTRAMURAL RESEARCH PROGRAM AWARDS FOR THREE NIH INSTITUTES *

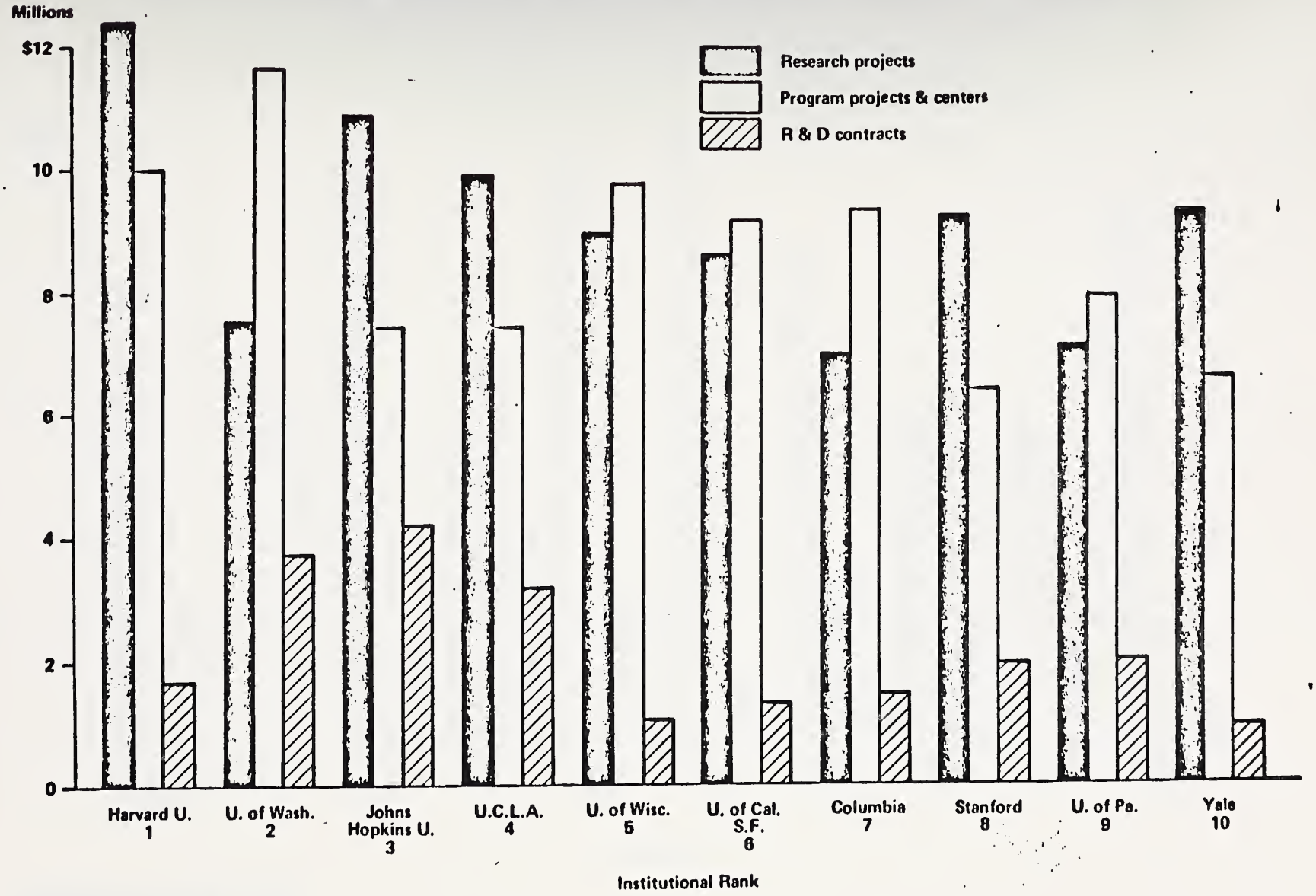
FISCAL YEAR 1967 & 1974 EST.



*INCLUDES I/RDs ONLY. EXCLUDES NIMH (AND NIMH PORTION OF GRS PROGRAM).

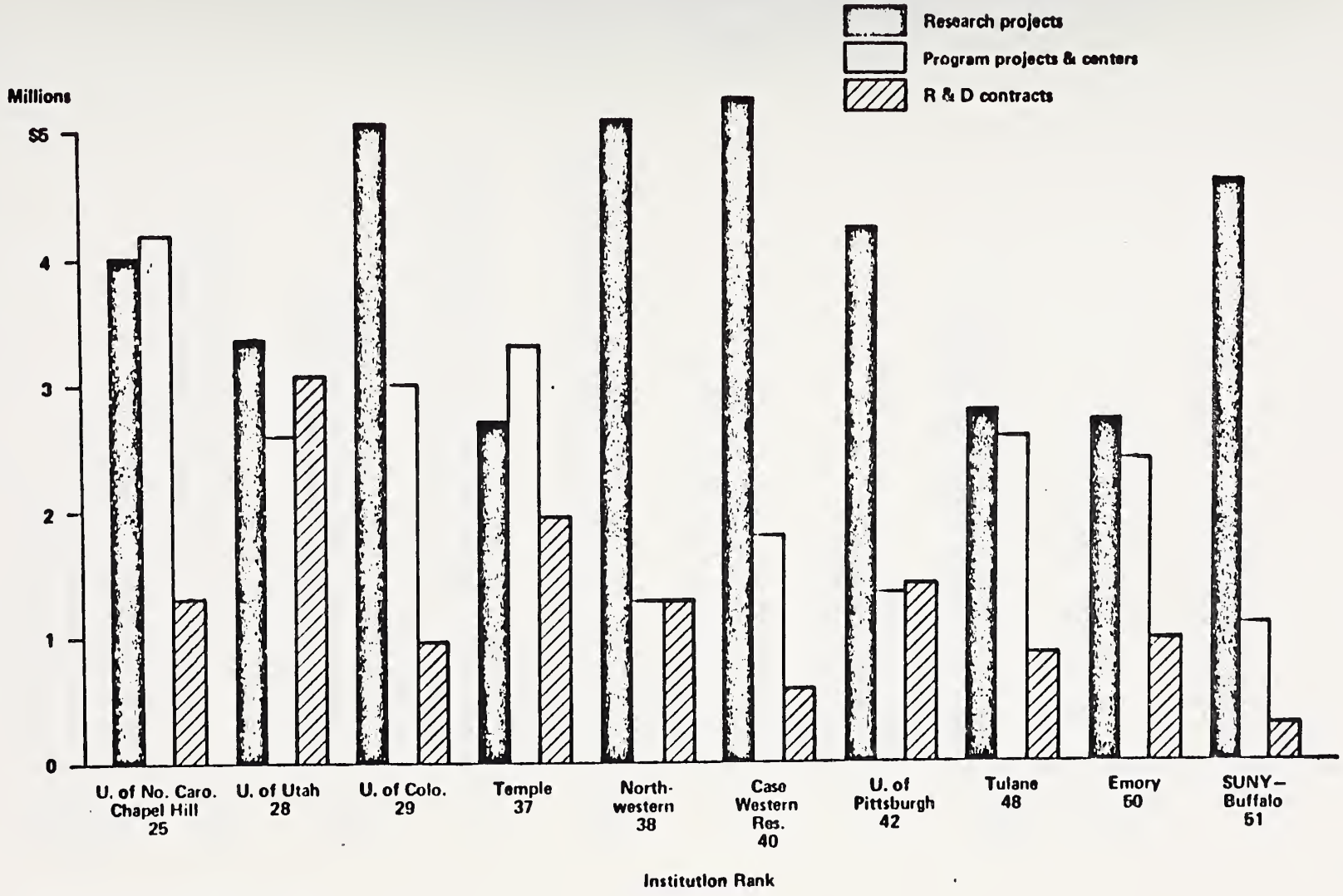
†EXCLUDES FUNDS WITHHELD IN FY 1973 AND RELEASED FOR USE IN FY 1974.

RELATIVE NIH RESEARCH-G...NT AND CONTRACT SUPPORT AMONG TOP 10 GRANTEE INSTITUTIONS, FY 1973*



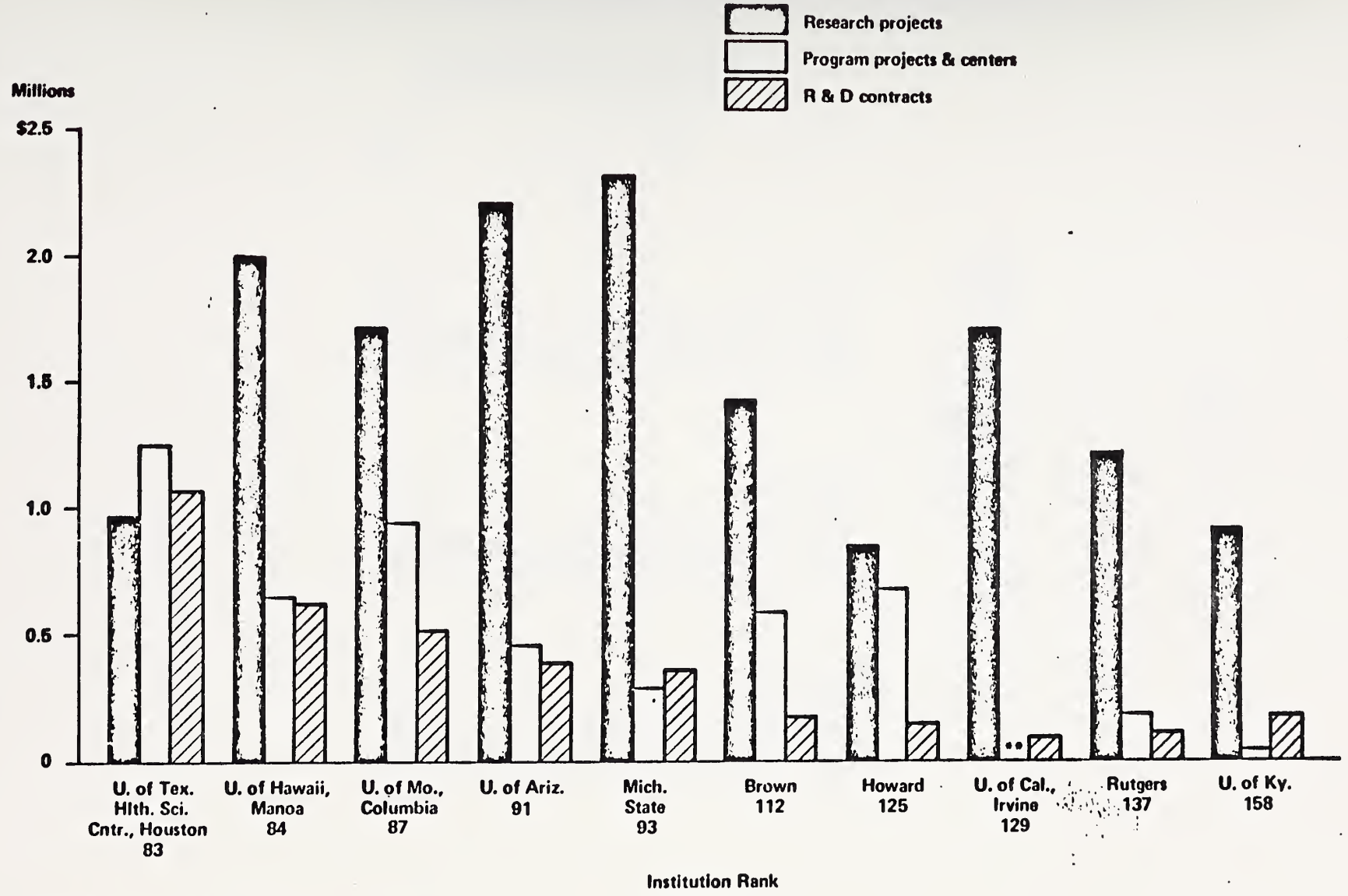
*Excludes funds withheld in FY 1973.

RELATIVE NIH RESEARCH-GRANT AND CONTRACT SUPPORT AMONG 10 SELECTED UNIVERSITIES RECEIVING $6 - 10 MILLION, FY 1973 *



*Excludes funds withheld in FY 1973.

RELATIVE NIH RESEARCH-GRANT AND CONTRACT SUPPORT AMONG 10 SELECTED UNIVERSITIES RECEIVING $1 - 3.5 MILLION, FY 1973*



*Excludes funds withheld in FY 1973.
**No funds awarded.

Slide 16

NATIONAL INSTITUTES OF HEALTH
BUDGET AUTHORITY, FY 1973-75
By Program

Program	FY 1973 (comparable)	FY 1974 (comparable)	FY 1975 President's Budget
Cancer	$ 485.2	$ 527.4	$ 600.0
Heart	287.9	286.7	309.3
Dental	45.8	43.9	44.0
Arthritis	158.3	153.1	153.0
Neurology	124.5	120.0	120.0
Allergy	107.7	110.5	110.4
General	173.8	166.8	168.3
Child Health	126.0	125.0	124.9
Eye	36.8	40.0	39.9
Env. Health	30.3	28.3	28.7
DRR	135.8	126.9	82.7
FIC	4.6	4.8	4.8
NLM	28.4	26.3	27.7
Other	20.4	21.0	21.1
Total	$1,765.5	$1,780.7	$1,834.8

Slide 17

NATIONAL INSTITUTES OF HEALTH
BUDGET AUTHORITY, FY 1974-75
By Mechanism

Mechanism	FY 1974 (comparable)	FY 1975 President's Budget
Research programs	$1,471.7	$1,530.4
Regular grants	684.8	706.8
GRS grants	52.2	7.3
Other res. grants	237.8	273.5
Labs & clinics	155.6	165.3
R & D contracts	296.0	325.8
Other direct res.	45.3	51.7
Research training	137.0	122.3
Grants	96.9	61.1
Fellowships	40.1	61.2
Cancer construction	27.5	22.0
Cancer control	34.1	45.1
NLM	26.3	27.7
Program management	63.1	66.2
Other	21.0	21.1
Total	$1,780.7	$1,834.8

GRANT OR CONTRACT?
Criteria for Determining Instrument of Choice

Grant	*Contract*
Project conceived by investigator	Project conceived by NIH
NIH supports or assists	NIH procures service or product
Performer defines details and retains scientific freedom	NIH exercises direction or control
NIH maintains cognizance	NIH closely monitors

GRANT VS. CONTRACT
Type of Project Generally Supported

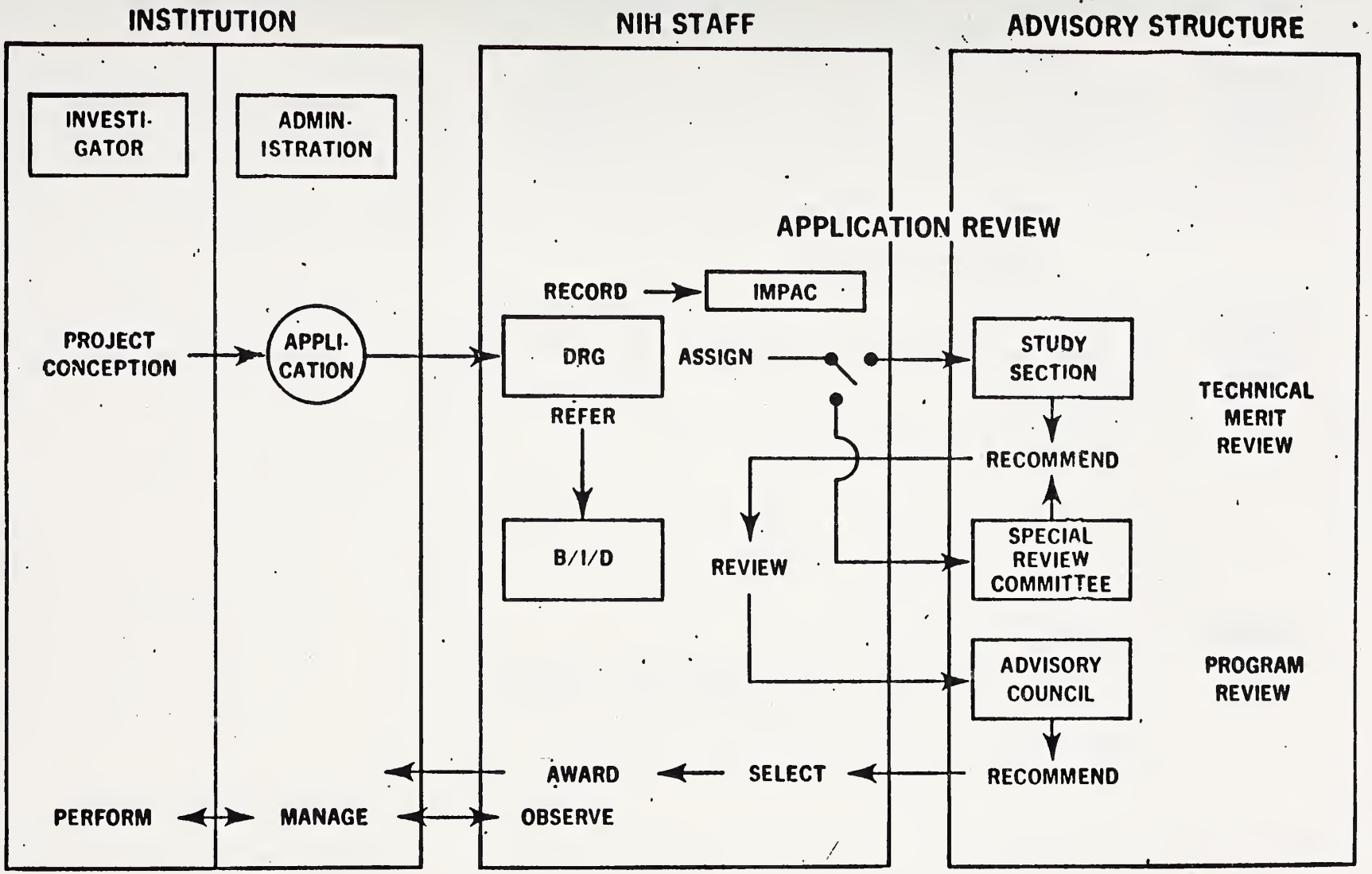
Grant		*Contract*
Fundamental research		Development
	Applied research	
Institutional support and training		Multi-institutional clinical trials, etc.
	Support of resources and facilities	

GRANT VS. CONTRACT
Some Contrasting Project Characteristics

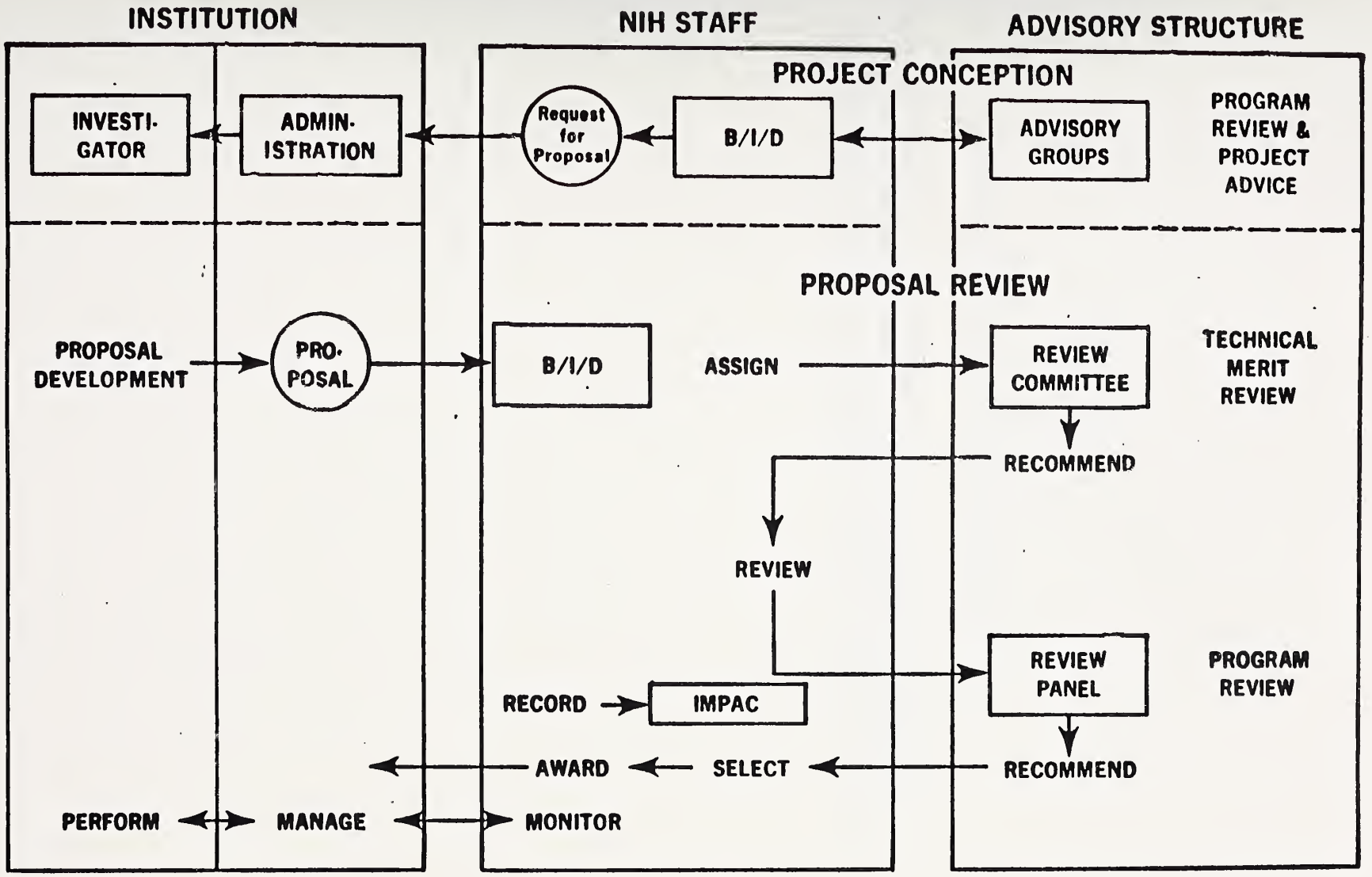
Grant	*Contract*
Diversified program	Targeted program
Exploratory project	Developmental project
Outcome defined but unpredictable	Outcome predictable
Extends knowledge base	Applies existing knowledge
Flexible approach	Structured approach
Simple NIH management	Intensive management
Difficult evaluation	Easy evaluation
Single institution	Multiple performers
Few people involved	Many people involved

Slide

REVIEW PROCESS FOR NIH EXTRAMURAL AWARDS - GRANTS



REVIEW PROCESS FOR NIH EXTRAMURAL AWARDS - CONTRACTS



Slide 23

PROGRAM MECHANISMS COMMITTEE RECOMMENDATION 2

⇨ That NIH establish and refine the use of uniform policies and standard procedures by which its components define, develop, and implement programs, and initiate, review, select, and manage projects funded by contracts, grants, and other awards--

TAB 9

Background for Answers to Questions to be Discussed at the

PUBLIC AFFAIRS SYMPOSIUM
OF THE
JOINT NATIONAL MEETING
OF THE
AMERICAN SOCIETY FOR BIOLOGICAL CHEMISTS
AND THE
BIOPHYSICAL SOCIETY*

BY

Robert S. Stone, M.D.**

*Minneapolis, Minn., June 5, 1974.

**Director, National Institutes of Health, U.S. Dept. of Health, Education, and Welfare.

Preface

There are several major theses implicit in all of my remarks, and while they are well known to most of you, it will do no harm to make them explicit. (Slide 1.)

The NIH is a health organization, charged with the mission of conducting research to control human diseases and disability. Research in the biological and medical sciences is the necessary means to attain this objective, since the outcome of past research completely defines the present state of knowledge related to health, as well as its derivative, the capability of the Nation's health-care delivery system.

Based on these premises, the NIH conducts scientific research at Bethesda and supports it elsewhere through grants and contracts. It should be emphasized that Federal support for basic research in the biomedical sciences is not provided to acquire knowledge for its own sake, but rather for eventual application to improvement of the Nation's health.

The allocation of Federal funds among the many competing claims for each dollar must be a political judgment. The task of the political system is to assess the social needs of the Nation and the willingness of the citizenry to be taxed for such needs. On the basis of these judgments, Federal revenue is raised and allocated for expenditure. In the case of the NIH budget, the political process allocates funds to each of the component research Institutes and, to an increasing extent, to specific programs within them.

Scientists and learned societies can have a role in the decision-making process by providing information that will assist the Government and the public to make rational and knowledgeable allocations. The questions posed to the members of this panel explore several dimensions of participation by the scientific community.

Slide 1.

- The NIH is a *health* organization. The end is health; the means, science.
- The allocation of Federal funds must be a *political* judgment.
- The *public* must be persuaded that the support of science benefits them.

Questions 1 and 3

1. Can the country effectively determine from among various competing priorities the proper allocation of national funds to basic scientific research in accordance with the long range national goals? One possible way to achieve this is by the establishment of a national commission on science composed predominantly of non-scientists with responsibility for making societal and political recommendations about science as a national priority. In your opinion, is such a commission politically feasible?

3. Can the government and the scientific community find a more effective way to distribute funds among various scientific disciplines and specific programs? One possible course would be through the establishment of a Council of Science and Technology advisors to advise the executive and legislative branches of government on such matters. Do you see a meaningful role for such a council?

The questions of how much Federal funding to allot to science and how these funds should be distributed among various scientific disciplines are clearly interrelated. Again, both decisions must, in the final analysis, be made by the executive and legislative branches of the Government acting through well-established political processes. Both branches recognize the need for expert scientific opinion and seek this from both within and without Government. The National Science Foundation has, since the abolition of the Office of Science and Technology, taken over that organization's responsibilities as the President's overall official advisor on questions of science policy and priority. The Congress has no official advisory body but uses experts ad hoc; the traditions and practices of various Congressional Committees vary over a considerable range.

Individual scientists as well as more-or-less well-organized and official groups of scientists presently insert their views into the Government decision-making process. The proposed "National Commission on Science" (Question 1) and the "Council of Science and Technology Advisors" (Question 3) are both feasible. The important issue--their usefulness--would depend on the intellectual force and persuasiveness of their views and on the credibility of their positions.

The proposition to establish a "National Commission on Science," composed predominantly of non-scientists, with responsibility for making societal and political recommendations about sciences as a national priority, would appear to encompass many of the functions which the Office of Management and Budget now performs for the President, and which the Congressional Appropriations Committees now carry out for the legislature. A number of questions concerning the jurisdiction of the proposed National Commission on Science would have to be resolved. For instance: What would be different about the National Commission on Science? How would it be constituted? To whom would it tender

recommendations? How would it operate? How much staff support could it have? If advisory to the President, how would differences with OMB be adjudicated? If advisory to the Congress, what unique point of view would it provide?

With regard to the suggested Council of Science and Technology Advisors, the same questions and reservations expressed earlier would be largely applicable. An additional factor is introduced, though, when the distribution of funds between sciences is considered. This factor is the relationship between the scientist and his academic discipline. It is doubtful that a scientist will recommend that his discipline should receive a lower proportion of the funds or grow at a slower rate than other scientific areas. Furthermore, if he should support such a recommendation, it is questionable that he would represent the discipline for any extended period.

Question 2.

Can the support of science be related to the country's economy on a regular and long-term basis? One way to accomplish this would be to establish a formula for financing science as a percent of the gross national product. This percentage, for example, could be recommended by the commission proposed above on a biannual or quadrennial basis. Would you favor such a plan?

The question concerns the feasibility of relating the support of science to the country's economy. It is generally felt in Government, however, that coupling the level of science support to any formula, even if revised often, is not a sound concept. Pragmatically speaking, such a proposal is probably not politically feasible; the Congress and the President have traditionally been unwilling to be committed to some automatic level of expenditure. Their operational assumption is that science support should be examined in detail every year and evaluated in light of other priorities. In short, both want to do their proper job.

From the point of view of biomedical research, too, the formula approach is questionable. Admittedly, it would be nice to have a guarantee that funds will always be allocated to this domain of science, but the historical record suggests little real reason for concern. (Slide 2.) The funds allotted to supporting biomedical and health research have grown faster than the GNP since World War II. We see that Federal biomedical research expenditures as a fraction of GNP have outpaced total Federal R&D expenditures, which have lagged as a result of the relatively decreasing committment to space and defense R&D.

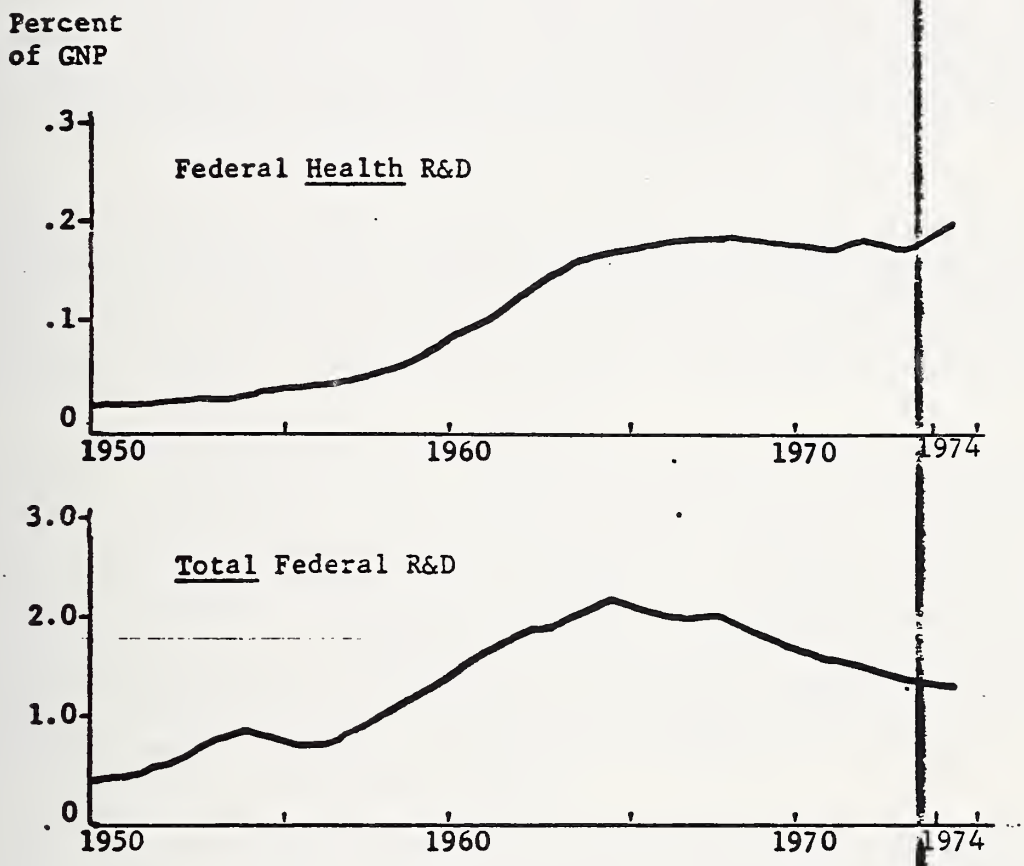
While the rate of growth has dropped recently because of other pressures on the Federal budget, the prime importance of biomedical research to national well-being and prestige makes it improbable that expenditures for this purpose will suffer drastic declines. Furthermore, a fixed formula could limit expenditures for research in the future, when expansion might otherwise occur, thus actually hobbling the Nation's biomedical and health research effort. Scientists might remember that the non-formula annual budget development process for Federal funding of biomedical research, although possibly disadvantageous, has worked well for a long time.

An annual budgetary review permits the public exposure and debate so necessary for public committment and serves as a wonderful opportunity for Federal science agencies to present their case to the topsides of their departments, to the OMB, and to the Congress. The process also offers non-Federal scientists, individually or through their societies, an opportunity to present their cases. All in all, it is an invaluable opportunity for the education of all participants. It is most

important, incidentally, for scientists and scientist administrators to become educated about the political processes and to gain understanding about the criteria for choice that operate in this arena.

Slide 2.

Federal Health R&D and Total Federal R&D
as Percent of Gross National Product



MAJOR HIGHLIGHT:

Increase in relation to GNP, 1950-1974
Federal Health R&D: 7.5 times
Total Federal R&D: 3.7 times

Question 4.

Can the government and the scientific community assure that the concepts of investigator-initiated research and management by objective are viewed as complementary and not as mutually exclusive? One important aspect of this is to assure that both programs receive adequate peer review. Do you favor identical review mechanisms for evaluation of the merits of grants and contracts? The training of future scientists should be viewed both as an educational program and as a supportive mechanism for research. Can adequate funding for training be assured?

This question assumes--I believe fallaciously--that the NIH considers investigator-initiated and contract research as equally good and useful means to achieve any scientific research purpose. Nothing could be farther from the truth. The purposes for which each is utilized are different, and hence, they have long been viewed as complementary means for conducting federally sponsored research.

Generally speaking, the NIH uses the contract when the consensus of experts is that a coordinated and directed focus of effort and funds will, with a high degree of probability, yield a specified and significant result. Some types of research proposal do not meet the criteria that make the research contract the appropriate mechanism for support. By its very nature, fundamental research simply cannot guarantee a predictable outcome. Furthermore, investigators engaged in such research should have a high degree of freedom to follow whatever unexpected leads emerge. Fundamental research historically provides useful knowledge, and the Government encourages it through the instrumentality of the research grant.

Since these two instruments for supporting research differ in method and purpose, each demands an appropriate and adequate review mechanism. The fact that the review mechanism for contract-supported research differs from that for grant-supported research does not necessarily mean that one system is better than the other. The NIH wishes to bring to bear on all the research it sponsors the best possible scientific advice.

Turning to the question of support for graduate education in the biomedical sciences, it is clear that this process simultaneously contributes directly to the national research effort and to the creation of the future supply of research scientists. It seems to me, at this time, that all of us--the academic community and the Federal Government--face a serious policy dilemma:

- If graduate education continues to generate Ph.D.s at the rate attained in the last several years, there are likely to be insufficient career opportunities for them once they complete

their training. (I am increasingly impressed by the studies of Alan Cartter and his colleagues.)

- On the other hand, if graduate education is throttled, how will the prevailing levels of research be maintained?

A resolution of this dilemma is not presently obvious to me. We must all ponder deeply the ethical problems related to positive intervention into the magnitude of the process of graduate education. There is inherent momentum in this process, irrespective of Federal student aid. Ph.D. production will undoubtedly continue at substantial levels under almost any foreseeable circumstance. A more proper role for the Government may conceivably be to concern itself more with quality than quantity in the immediate future.

Question 5.

What constructive steps can the learned societies take to convey to the government and the public the importance of biological research in dealing with problems related to health, agriculture, energy, etc.? Currently plans are being developed to establish a "Biology Alliance in Public Affairs" to act as an advocate of the role of biological research in public matters. This umbrella organization of 10-12 societies will represent 30-40,000 biologists. Could such an organization be useful to you in your official capacity?

Obviously, an effective advocate of the importance of biological research would be helpful to the Director of the National Institutes of Health, particularly in generating more widespread public understanding.

The public's willingness to persist in the support of biomedical research at the necessary level is ultimately determined by the prospect of benefits.

The "Biology Alliance in Public Affairs" could be most helpful by demonstrating to the public the essential linkage between scientific discovery and progress against disease. Such a group could help to interpret the nature of the scientific endeavor and the significance of the pursuit of basic knowledge in the context of disease prevention, treatment, and cure.

Non-government scientists can be effective as advocates in providing information to the Congress and the Administration, but over the long pull, it is the public which must be persuaded that the support of science is a means for achieving public good. The significance of the scientific community is not its numerical size. Speaking solely for its own interests, it would have little impact.

Question 6.

Can the research oriented societies play a meaningful role in the process of assessing current and future national needs with respect to biological resources; i.e., manpower, research facilities and appropriate project support? What advice can you offer us, the nation's biochemists and biophysicists, on how we can apply our insights and expertise to serve the nation?

The research-oriented societies can play a meaningful role in the process of assessing current and future needs with respect to biological resources.

Government officials who head research programs are to some degree limited in the effectiveness of their advocacy by appearing to be self-serving in doing what is expected of them--that is, strongly supporting their own programs.

The same limitation, to a lesser extent, applies to members of the scientific community whose interests are aligned with the Federal support of science.

Research-oriented societies can be indispensable sources of information about science and its needs. However, their participation in the realm of national policy should be subject to the same standards of quality that scientists apply to their own work. To gain and maintain influence, such organizations must accept the burden of becoming expert in the policy matters on which they speak out. I would encourage their development of adequate staffing as an essential step toward their recognition in all quarters as objective, thorough, and reputable spokesmen for science. This would be beneficial indeed.

TAB 10

NOTES FOR "FOCUS ON HEALTH"*

Dr. Robert S. Stone, M.D.**

Many of you are very familiar with our organization, others less so. The first slide outlines some recent history.

The next slide (2) represents the present organization.

- At the top we see the health components of DHEW [already discussed by others].
- NIH contains 11 National Institutes.
- The Cancer and Heart Institutes are shown separately to indicate their status as Bureaus.
- The research Divisions--those with major research programs, intramural or supportive--are FIC and DRR.
- The other Divisions, most of which conduct some research of their own, are primarily dedicated to the service of NIH operations.

The next slide (3) represents appropriations for the year that ended June 31. It will give some idea of how the several Institutes and research Divisions (the I/RDs) approach their missions. In general, NIH activities include both the support of research and the development of biomedical scientists and institutions. To carry out these functions--

*Orientation program at NIH for science writers, 7/11/74.

**Director, National Institutes of Health, U.S. Dept. of Health, Education, and Welfare.

- Cancer, Heart, and Child Health have relatively large contract programs; Arthritis and Neurology, relatively small ones.
- General Medical Sciences, Research Resources, and Fogarty International Center conduct no direct research.
- In the right-hand panel, we see NCI's contruction and control programs--the only such operations now at NIH.
- Support of program projects and centers is prominent in Cancer, Heart, General Medical Sciences, and Research Resources, while very limited in Arthritis, Allergy and Eye.
- Research Resources administers the GRS program--formula grants to institutions, much curtailed in the current budget.

Shifting from appropriations to obligations, or actual funding, we see in the next slide (4) the major trends of the past two decades in terms of mechanisms of support. Programs no longer with NIH are excluded--Mental Health, Biologics Standards, Health Manpower Education. With minor exceptions, we are looking at research and research training.

The fiscal 1974 estimate (we still do not have final figures) is represented by two bars--the funds withheld in '73 and released for use last year, and the '74 appropriation.* Mainly because of the '73 funds, total obligations for last year, estimated at more than $2 billion, exceed the appropriations shown in the last chart.

"Research," running about 80 percent of the program, includes direct and collaborative activities, regular grants, general research support grants, and special grants (program projects and centers).

*Less than the actual appropriation by about $69 million, due mainly to a 5 percent cut (reserve) which was later restored.

Total grants in 1973 and '74 comprised about 65 percent of the budget. R & D contracts (mostly in the collaborative programs) accounted for 17 percent of all NIH funds. Research construction grants, once a $100 million program, are now limited to cancer construction--$34 million last year.

Now I'd like to switch from budget matters to the review system for awarding grants and contracts. [Slide, please (5).] There are many criteria that determine whether research is to be financed by one or the other mechanism, but the principal difference is whether NIH is funding a project or buying a product. The grant, a conditional gift, is favored when the research project is definable, but the outcome unpredictable; while the contract usually looks toward a predictable result. Again, the grant tends to be used when the ideas originate with the investigator, the contract when they arise at NIH. This slide and the next one contrast the reviews of proposals under these two support mechanisms.

Here we see the elements of the NIH review process for grants.

- The black portions are the common ground in the review of both grants and contracts.
- Green indicates procedure applicable only to grants, though sometimes the difference is largely semantic--"application" vs. "proposal"--or structural--"Bureau/Institute/or Division" vs. "Division of Research Grants."

The next and last slide (6) shows the review process for contracts.

- The procedure applicable to contracts is shown in red.

- The part above the dotted line is unique to contracts, in that it represents the flow of ideas from NIH toward the investigator.
- Below that point, there is little real difference between this process and the previous one, except that the advisory structure is largely intramural.

In NIH programs today, an attempt is under way to formalize the review and advisory process in respect to contracts, with a view to ensuring the same degree of expertise and objectivity as the grant programs have always received.

NOTE: The attached charts were not used by Dr. Stone. He used,however, the following:

Slides on the historical growth of NIH buildings (S-2 thru S-2D).

Postwar development of NIH programs.

History of NIH (1971 - 1974) (See S-150F)

Organization of NIH.

NIH obligated funds by function (S-61).

NIH appropriations (S-51G).

Grant or contracts? Criteria for determining instrument of choice (S-73).

Grant vs. contract. Type of project generally supported (S-74).

Grants vs. contract. Some contrasting project characteristics (S-75).

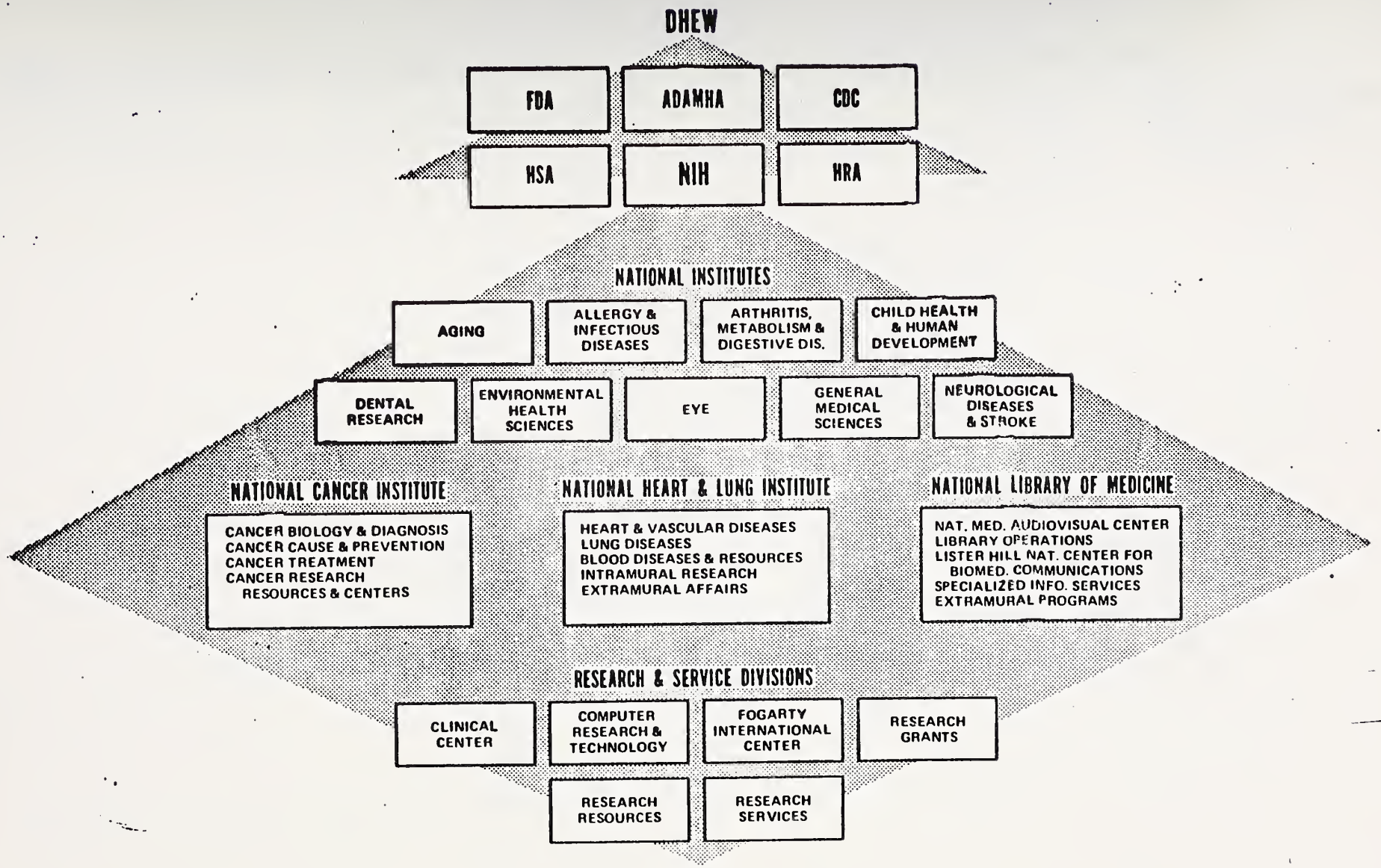
Review process for NIH extramural awards--grants (S-76).

Review process for NIH extramural awards--contracts (S-77).

Slide 1

1971	National Cancer Program Instituted.
1972	NIAMD becomes National Institute of Arthritis, Metabolism and Digestive Diseases. Biologics Standards transferred to FDA. NCI and NHLI gain bureau status within NIH.
1973	PHS reorganized. Bureau of Health Manpower Education transferred out of NIH (but not its Division of Research Resources).
1974	National Institute on Aging established.

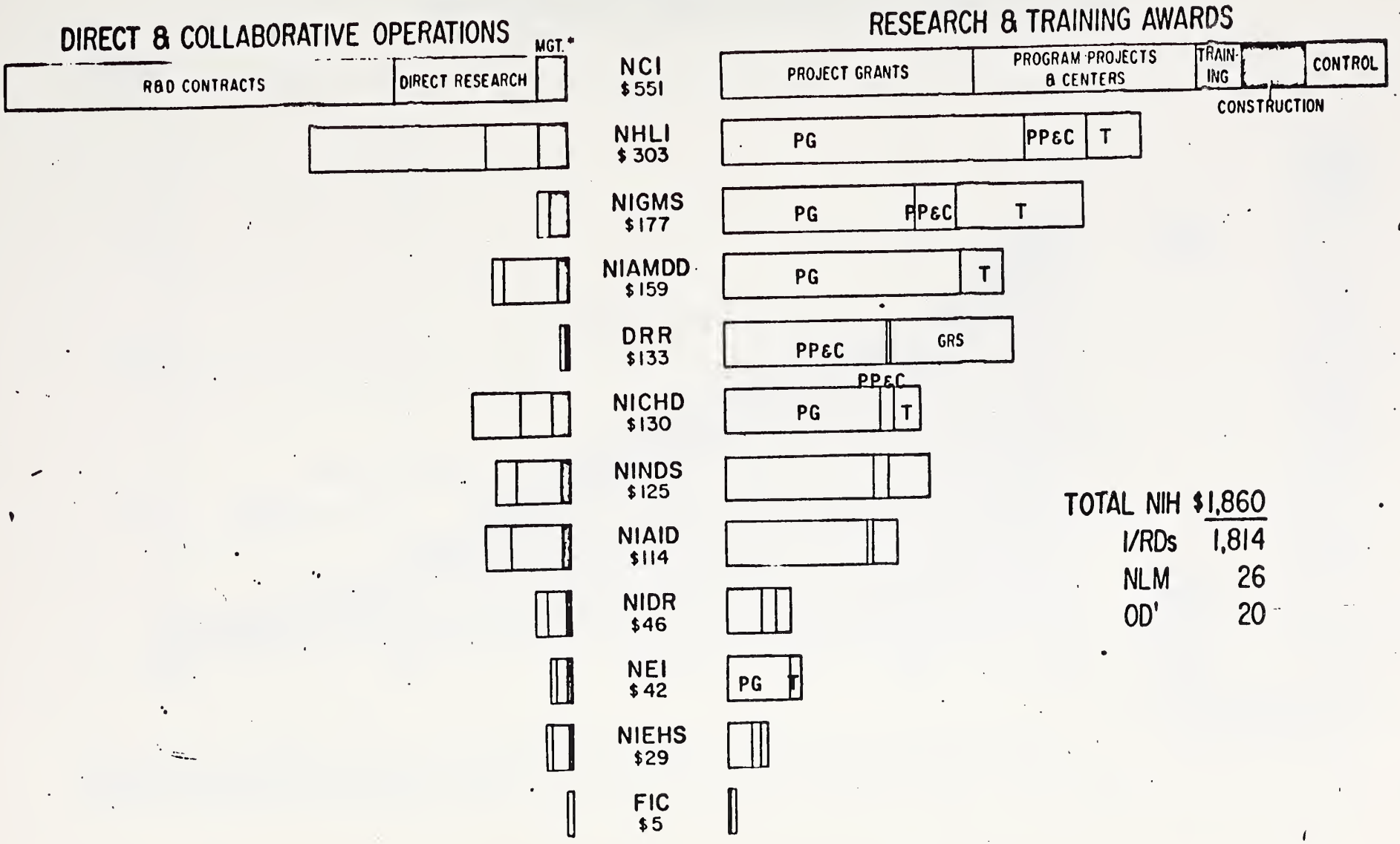
Slide


DHEW
FDA
ADAMHA
CDC
HSA
NIH
HRA
NATIONAL INSTITUTES
AGING
ALLERGY & INFECTIOUS DISEASES
ARTHRITIS, METABOLISM & DIGESTIVE DIS.
CHILD HEALTH & HUMAN DEVELOPMENT
DENTAL RESEARCH
ENVIRONMENTAL HEALTH SCIENCES
EYE
GENERAL MEDICAL SCIENCES
NEUROLOGICAL DISEASES & STROKE
NATIONAL CANCER INSTITUTE
CANCER BIOLOGY & DIAGNOSIS
CANCER CAUSE & PREVENTION
CANCER TREATMENT
CANCER RESEARCH RESOURCES & CENTERS
NATIONAL HEART & LUNG INSTITUTE
HEART & VASCULAR DISEASES
LUNG DISEASES
BLOOD DISEASES & RESOURCES
INTRAMURAL RESEARCH
EXTRAMURAL AFFAIRS
NATIONAL LIBRARY OF MEDICINE
NAT. MED. AUDIOVISUAL CENTER
LIBRARY OPERATIONS
LISTER HILL NAT. CENTER FOR BIOMED. COMMUNICATIONS
SPECIALIZED INFO. SERVICES
EXTRAMURAL PROGRAMS
RESEARCH & SERVICE DIVISIONS
CLINICAL CENTER
COMPUTER RESEARCH & TECHNOLOGY
FOGARTY INTERNATIONAL CENTER
RESEARCH GRANTS
RESEARCH RESOURCES
RESEARCH SERVICES

Slide 3

NIH APPROPRIATIONS, FY 1974

(in millions of dollars)



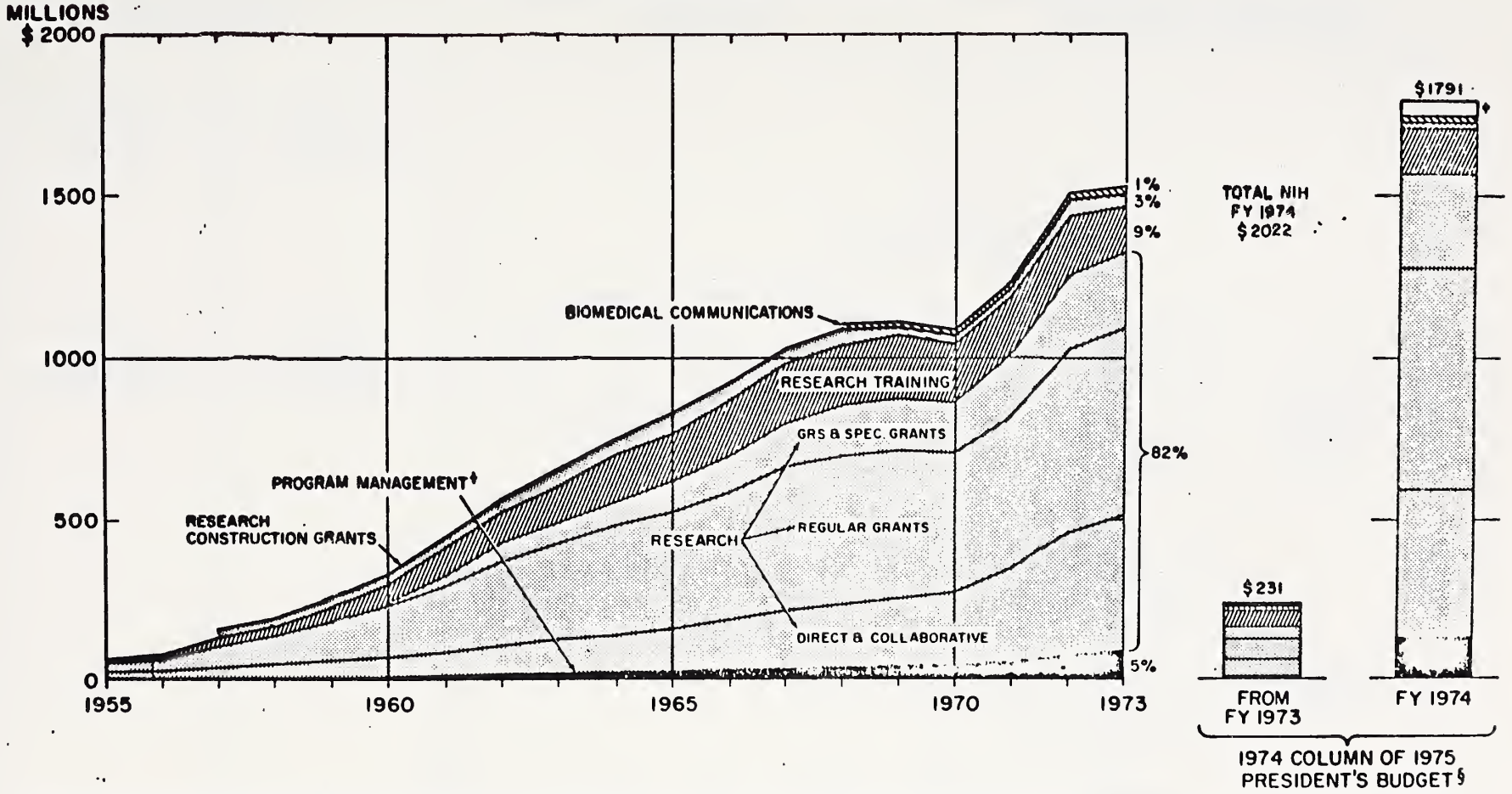
TOTAL NIH	$1,860
I/RDs	1,814
NLM	26
OD'	20

*Program management, including scientific evaluation. 'Includes salaries, expenses, NIH buildings.

Slide 4

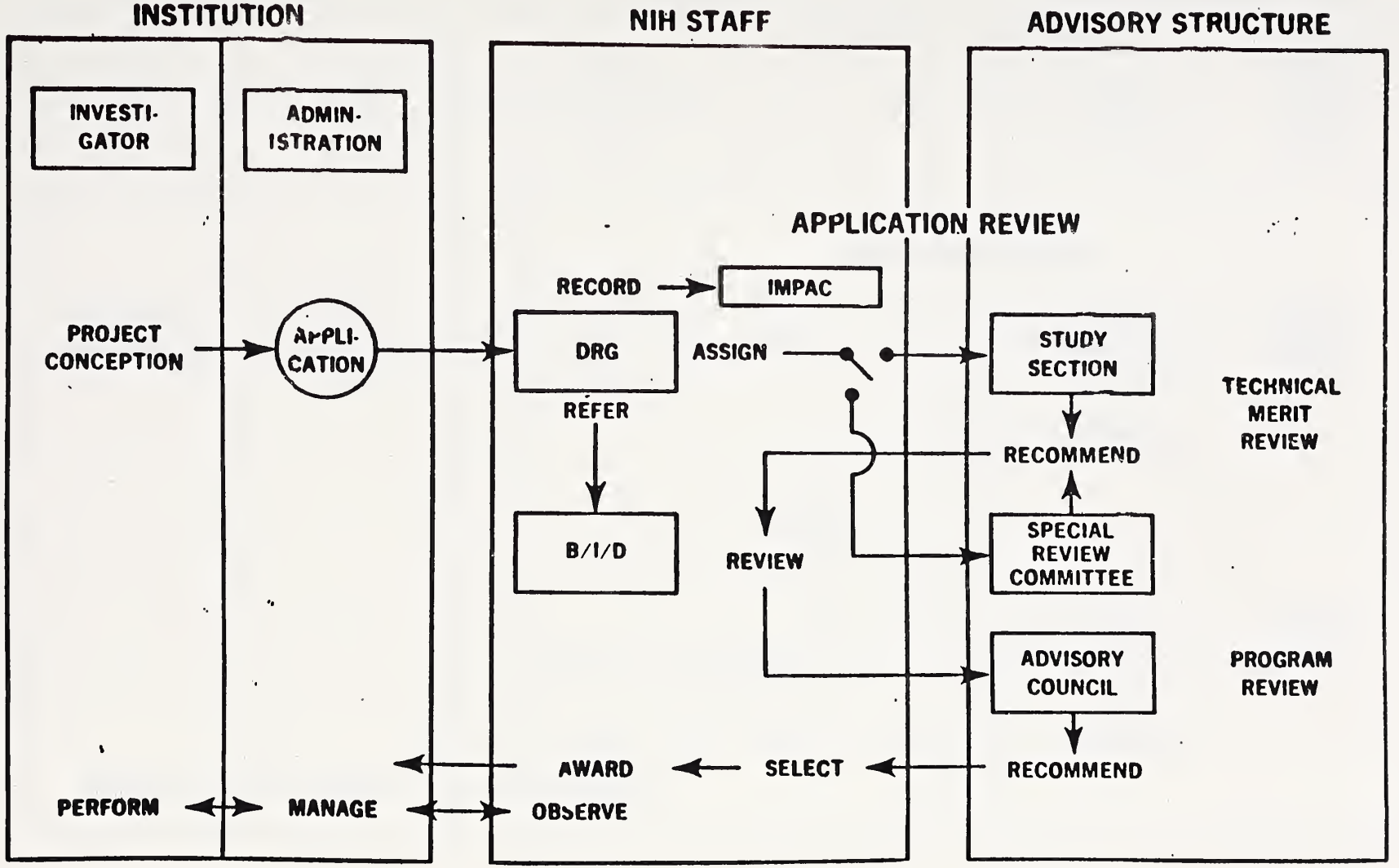
NIH OBLIGATED FUNDS BY FUNCTION, FY 1955-1974 EST.

EXCLUDING PROGRAMS THAT HAVE BEEN TRANSFERRED OUT *



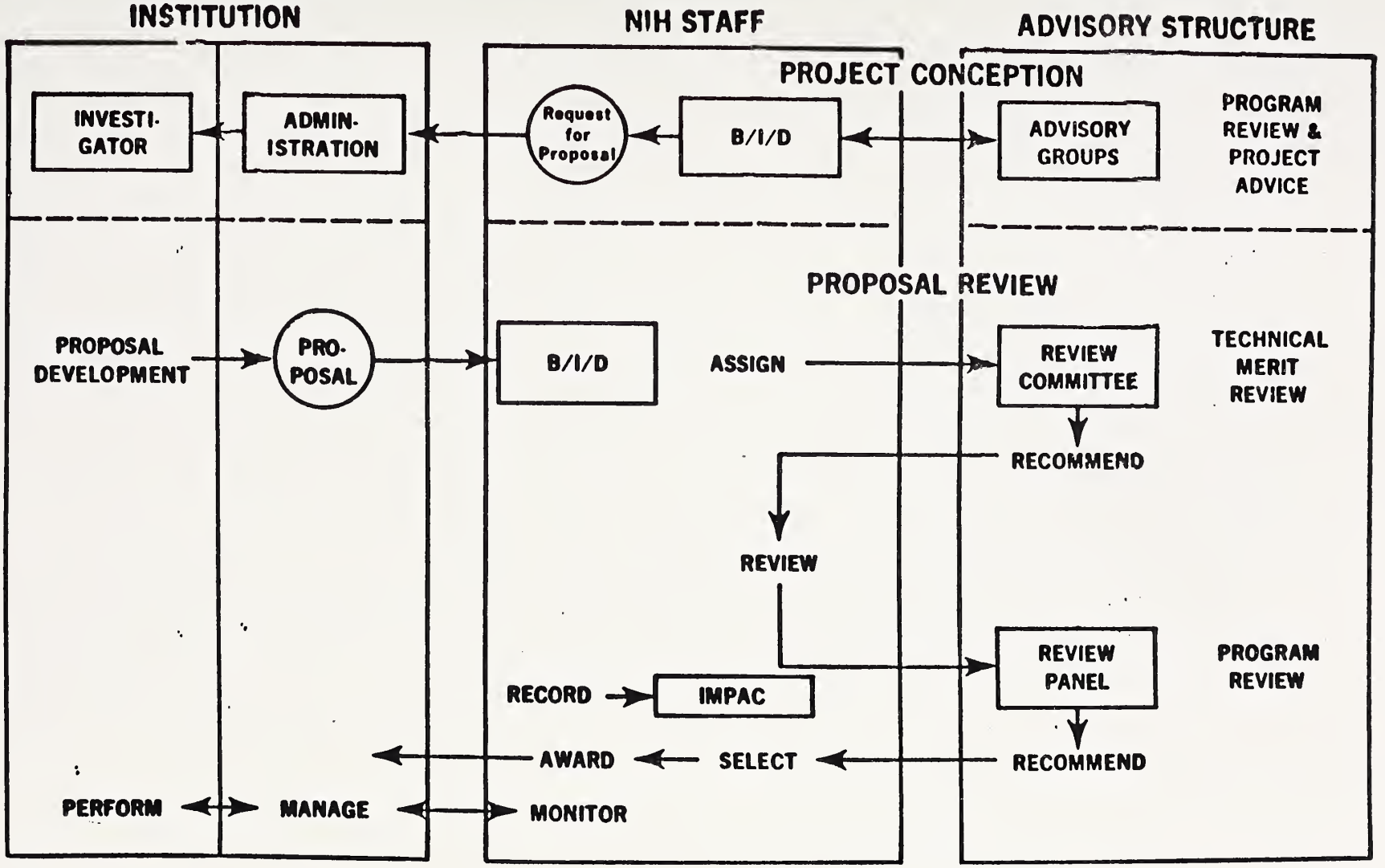
* NIMH, COMMUNITY PROGRAMS, DBS AND BHME. ALSO EXCLUDES FOREIGN CURRENCY PROGRAM. INCLUDES NLM FROM FY 1968 ON.
† INCLUDES BUILDINGS AND FACILITIES FROM FY 1969 ON. BUT CHART EXCLUDES DIRECT CONSTRUCTION FOR PRIOR YEARS. ‡ CANCER CONTROL.
§ EXCLUDES NIMH SHARE OF GRS GRANTS, $8.0 MILLION.

REVIEW PROCESS FOR NIH EXTRAMURAL AWARDS - GRANTS



Slide 6

REVIEW PROCESS FOR NIH EXTRAMURAL AWARDS - CONTRACTS



TAB 11

9/18/74

BIOMEDICAL RESEARCH AND THE NATIONAL INSTITUTES OF HEALTH*
(Outline)

Robert S. Stone, M.D.**

I. Introduction.

A. Amenities.

B. The relationship of NIH to the biomedical research community will be affected in specific ways by recent and pending legislation and by sweeping changes in policy and procedures.

C. I believe we can best explore the topic "biomedical research and the NIH" by summarizing these developments and discussing their probable implications.

II. The most controversial issue of recent NIH history is that of its training grants--an issue stemming from the 1972 decision to phase out the program, followed by an expansion of fellowships for FY 1974.

A. The following slide (1) shows the obligated amounts for all research training awards in fiscal years 1968 through 1974 (President's Budget).

NIH TRAINING PROGRAMS, FY 1968-1974 est.
(In millions of dollars)

	1968	1969	1970	1971	1972	1973	1974
Training grants	$132.0	138.3	127.9	129.2	136.8	103.8	139.6
Fellowships*	27.7	29.8	22.8	23.7	21.9	12.2	49.5
Totals	$159.7	168.1	150.7	152.9	158.7	116.0	189.1

*Includes traineeships.

*Annual meeting, Association of Independent Research Institutes, Oklahoma City, Okla., 9/20/74.

**Director, National Institutes of Health, Public Health Service, U.S. Dept. of Health, Education, and Welfare.

B. The National Research Act of 1974, Title I (P.L. 93-348), which became law on July 12, consolidated all research training authorities of NIH and ADAMHA into a single National Research Service Award Authority.

C. The new law represents a Congressional response to the Administration's announced intention to phase out the training programs.

1. In his 1974 budget message to the Congress, President Nixon called for an immediate reduction or termination of several Federal health programs. Research training grants and fellowships would have no new starts.

2. Congress disagreed. The Rogers Health Subcommittee in the House and the Kennedy Subcommittee in the Senate introduced bills and held hearings to design legislation that would assure continuation of the training of scientists.

3. The Weinberger fellowships were instituted.

4. NIH research training funds that had been impounded in fiscal 1973 were released for use in 1974.

5. The new law was passed after much compromise and many revisions.

D. The next slide (2) enumerates main provisions of the law as regard training:

NATIONAL RESEARCH ACT OF 1974--Title I
(P.L. 93-348)

- National Research Service Awards replace training grants and fellowships.
- A minimum of 25 percent of appropriated funds must go for individual fellowships. The remainder may be spent on institutional awards.
- All trainees are now subject to service and payback obligations, except those under commitments made before July 12.
- Funds will go only to those fields in which there is need for research manpower, as determined by NAS.
- National Advisory Councils must approve all Research Service Awards.
- New guidelines and regulations will be announced.

E. The Act's probable impact on the biomedical research community remains to be seen. Two principal issues:

1. Will there be, under the new law, a change in the number of trainees applying for support?

2. Will there be adequate manpower for biomedical research in the future?

F. I will not discuss Title II of the Act, which creates a National Commission for Protection of Human Subjects, as Dr. Chalkley commented on that yesterday.

III. Another law that will have a significant impact on NIH and its grantees is the Congressional Budget and Impoundment Control Act, which revises the Congressional budgetary process. The next slide (3) shows some of the changes to be effected:

CONGRESSIONAL BUDGET AND
IMPOUNDMENT CONTROL ACT OF 1974
(P.L. 93-344)

- Establishes Senate and House Budget Committees, which will initially set levels of Federal spending, revenue, and budget deficit or surplus for the fiscal year.
- These committees may later direct changes in spending authorities, revenues, or the Federal debt ceiling prior to final Congressional action.
- Changes the fiscal year to begin October 1 (1976).
- Creates the Congressional Budget Office to provide budgetary expertise to Congress.
- Title X concerns impoundment control.
- Other major changes cover budget formulation and review, and establish procedures for obtaining legislative authority for Federal programs.

IV. Several recent Acts of Congress establish new programs at NIH. I'd like to take these up briefly.

A. The first in point of time is the Sudden Infant Death Syndrome Act of 1974, passed on April 22.

1. Main features are summarized in the next slide (4).

SUDDEN INFANT DEATH SYNDROME ACT OF 1974
(P.L. 93-270)

- Mandates NICHD to support research on SIDS.
- Requires detailed reports to the Congress, including estimates of the need for additional research funds.
- Provides for an information and counseling program at

$2	million	for	fiscal	year	1975
3	"	"	"	"	1976
4	"	"	"	"	1977.

2. Controversy has centered on whether a direct attack on SIDS or broader research on infant health would be the more productive.

3. The language of the Act encourages NICHD to expand its support of SIDS research, seeking to draw the institute into the field as research opportunities emerge.

4. Represents tendency of Congress to identify health problems for specific attack through categorical legislation.

B. The next slide (5) summarizes the Research on Aging Act of 1974, passed May 31.

RESEARCH ON AGING ACT OF 1974
(P.L. 93-296)

- Created the National Institute on Aging.
- Requires the Secretary to study through the Institute how the aged are affected by HEW programs.
- Requires the Secretary of HEW to develop a research plan on aging.
- Directs increased training of allied health workers and nurses for health care of the aged.

The new institute was earlier proposed in legislation passed by both Houses of the 93nd Congress, but was pocket-vetoed by the President.

C. The National Diabetes Mellitus Research and Education Act, passed July 23, had a long history closely monitored by NIAMDD. Expands the powers of that Institute to advance a national attack on diabetes. The next slide (6) gives highlights of the new authority.

NATIONAL DIABETES MELLITUS
RESEARCH AND EDUCATION ACT
(P.L. 93-354)

- Expands research attack on diabetes.
- Establishes National Commission on Diabetes to formulate a long-range plan.
- Calls for coordinating NIH and other programs to provide for

  --investigations into the cause, prevention, treatment and control of diabetes

  --education of scientists and other personnel

  --collection and analysis of data

  --development and evaluation of drugs and techniques

  --distribution of resources between basic and applied research.

[Next slide (7), please.]

NATIONAL DIABETES ACT Cont.

- Authorizes appropriations of

  $ 8 million for fiscal year 1975
  12 " " " " 1976
  20 " " " " 1977

  for diabetes research and training centers. Establishes an
- Associate Director for Diabetes in NIAMDD,
- Inter-Institute Diabetes Mellitus Coordinating Committee in NIH,
- Inter-Agency Technical Committee on Diabetes Mellitus to coordinate Federal programs.

[Next slide (8).]

V. Another Act of Congress with important implications for biomedical research is the National Cancer Act Amendments of 1974, enacted on July 23.

A. MAJOR FEATURES OF THE NATIONAL CANCER ACT AMENDMENTS OF 1974 (P.L. 93-352)

- Extends NCI programs for 3 years at

$750	million	for	fiscal	year	1975
830	"	"	"	"	1976
985	"	"	"	"	1977

- Extends NCI control programs for 3 years at

$53.5	million	for	fiscal	year	1975
68.5	"	"	"	"	1976
88.5	"	"	"	"	1977

[Next slide (9).]

B. NCI AUTHORIZATION FOR FY 1974-1977

1974	1975	1976	1977
$640*	803.5	898.5	1,073.5

*FY 1974 appropriation: $527.5 million.

It should be noted that the Panel of Consultants to the Senate in 1970 recommended a level of $800 million to $1 billion by 1976.

[Next slide (10).]

C. OTHER FEATURES OF THE NATIONAL CANCER ACT AMENDMENTS OF 1974 (P.L. 93-352)

- Expands information programs for practitioners, scientists and the public.
- Authorizes clinical trials of Pap tests.
- Authorizes NCI Director to award grants up to $35,000 in direct cost without approval by the National Advisory Council.
- Increases experts and consultants available from 50 to 100.
- Requires budget estimates of personnel needed for program.
- Authorizes grants for construction.
- Removes limit of 15 on number of comprehensive cancer centers.

D. Provides for establishment of a President's Biomedical Research Panel.

1. Provisions.

2. This generated some controversy. [Discuss.]

E. The next slide (11) represents the so-called anti-impoundment provision of the Cancer Act Amendments. This and two following provisions affect all NIH programs.

ANTI-IMPOUNDMENT PROVISION OF THE NATIONAL CANCER ACT AMENDMENTS OF 1974 (P.L. 93-352)

- Prohibits administratively imposed freezes, reductions and rollbacks of health programs.
- Requires that all funds appropriated under the PHS Act and related statutes remain available throughout the fiscal year.

F. Another provision of the Cancer Act, as shown in the next slide (12), confirms the contracting authority of the PHS.

CONTRACTING AUTHORITY UNDER THE
NATIONAL CANCER ACT AMENDMENTS OF 1974
(P.L. 93-352)

- PHS Act had furnished contracting authority for 8 years--1966 through June 30, 1974.
- House and Senate strongly supported an extension of the Secretary's authority (S. 2893 and H.R. 13053).
- P.L. 93-352 amended the PHS Act to remove the time limitations.

G. One other provision of the Cancer Act Amendments is summarized in the next slide (13).

PEER REVIEW REQUIREMENTS UNDER
NATIONAL CANCER ACT AMENDMENTS OF 1974
(P.L. 93-352)

- Mandates peer review of NIH and ADAMHA grants for biomedical and behavioral research.
- Mandates comparable review for R & D contracts.
- Grant applications must be conducted according to the current system and by peer groups as now constituted.
- Not more than one-fourth of such peers may be officers or employees of the United States.

VI. This strengthening of peer review provisions of the PHS Act coincides with measures now under way in all our programs to formalize the review of contracts, through mechanisms analogous to those long used for grants. The next two slides (14-15) compare and contrast the peer review under both instruments.

A. SLIDE 14: Review Process for NIH Extramural Awards--Grants.

1. The black portions are the points in common.

2. Green indicates procedure applicable only to grants, though sometimes the difference is largely semantic--"application" vs. "proposal"--or structural--"Bureau/Institute/or Division" vs. "Division of Research Grants."

B. SLIDE 15: Review Process for NIH Extramural Awards--Contracts.

1. Here the procedure applicable to contracts is shown in red.

2. The part above the dotted line is unique to contracts, in that it represents the flow of ideas from NIH toward the investigator.

3. Below that point, there is little difference between this process and the previous one, except that the advisory structure is partly intramural.

4. The advisory groups range from ad hoc to chartered, from 5 or 6 members to about 2 dozen, and from all staff to all extramural--but care is exercised in maintaining expertise and objectivity as the proposal moves from intramural conception to contractor formulation and back for review and selection.

5. Later monitoring of performance is an active staff role.

VII. This formalization and strengthening of peer review for NIH contracts is a natural accompaniment to the expansion, absolute and relative, of the contract programs.

A. The next slide (16) permits comparison of growth in all NIH grants and contracts.

1. The overall program has almost doubled since fiscal 1967.

2. The principal increases are in contracts and large grants.

3. Research projects have grown somewhat, but have considerably diminshed in relative terms, as seen in the percentage distribution.

4. This, as you know, has been a matter of concern in the scientific community, and we have given serious attention to the causes and implications.

B. The next slide (17) shows that the trend toward contracts and larger grants--that is, program projects and centers--is strongest in three institutes: National Cancer Institute, Heart and Lung, and Child Health and Human Development. These institutes are changing the way they do business.

C. The same data distributed by percent, as shown in the next slide (18), reveal the striking proportional decrease in

traditional grants for the three unusual institutes and the fairly steady state for the rest of the NIH research support program.

VIII. The expansion of our contract-funded research has given rise to some trepidations. There is concern that we may be shifting our support from the academic to the industrial, or profit, sector. The next slide (19) shows that this is not the case.

A. The several institute programs are represented at two points of time--fiscal 1969 and 1973.

1. Note that the scale for the two largest institutes is 10 times that for the others.

2. The Cancer Institute awards a much larger portion of its contracts to profit firms than do the other Institutes.

3. But we see from the next slide (20)--a percentage distribution of the same data--that NIH in toto, including NCI and most of the other programs, have decreased their relative contract support to profit organizations.

4. The next slide (21) isolates Cancer and Heart, by far the two largest institutes, and permits a view of the residual aggregate.

5. Relative support of profit organizations is seen to have declined for all the sets of bars.

B. Educational institutions continue to receive the bulk of the contract funds in all our programs, and even to be gaining over the other kinds of performers for NIH as a whole.

[Lights, please.]

IX. Conclusions: It is difficult to generalize about the changes in legislation and NIH administration that I have summarized today.

A. I believe we see an action-reaction pattern as between the Administration and the Congress.

1. Attempts on the part of the Administration to turn programs around, as in the case of training grants, or to emphasize certain health-problem areas, like cancer and heart disease, have led the Congress, often spurred by interested groups, to make its own power play.

2. New thrusts are urged against specific health problems--SIDS, aging, diabetes--and new safeguards are introduced, like the anti-impoundment measures.

3. There is emphasis on "plans" to be approved by Congress.

4. NIH strengthens its peer review of contracts--that is, quality control through the scientific community--in response to concern for research standards.

5. Congress mandates peer review of both contracts and grants.

B. It is not clear how all this will affect NIH or its constituency--the scientists of the Nation and their institutions.

1. In general, there is a propensity on the part of both the Administration and the Congress to increase support for biomedical research.

2. The support, however, is increasingly tailored, with more decisions on fund allocation being made through the political process.

3. There is a tendency to think in terms of program or activity rather than mechanism of support.

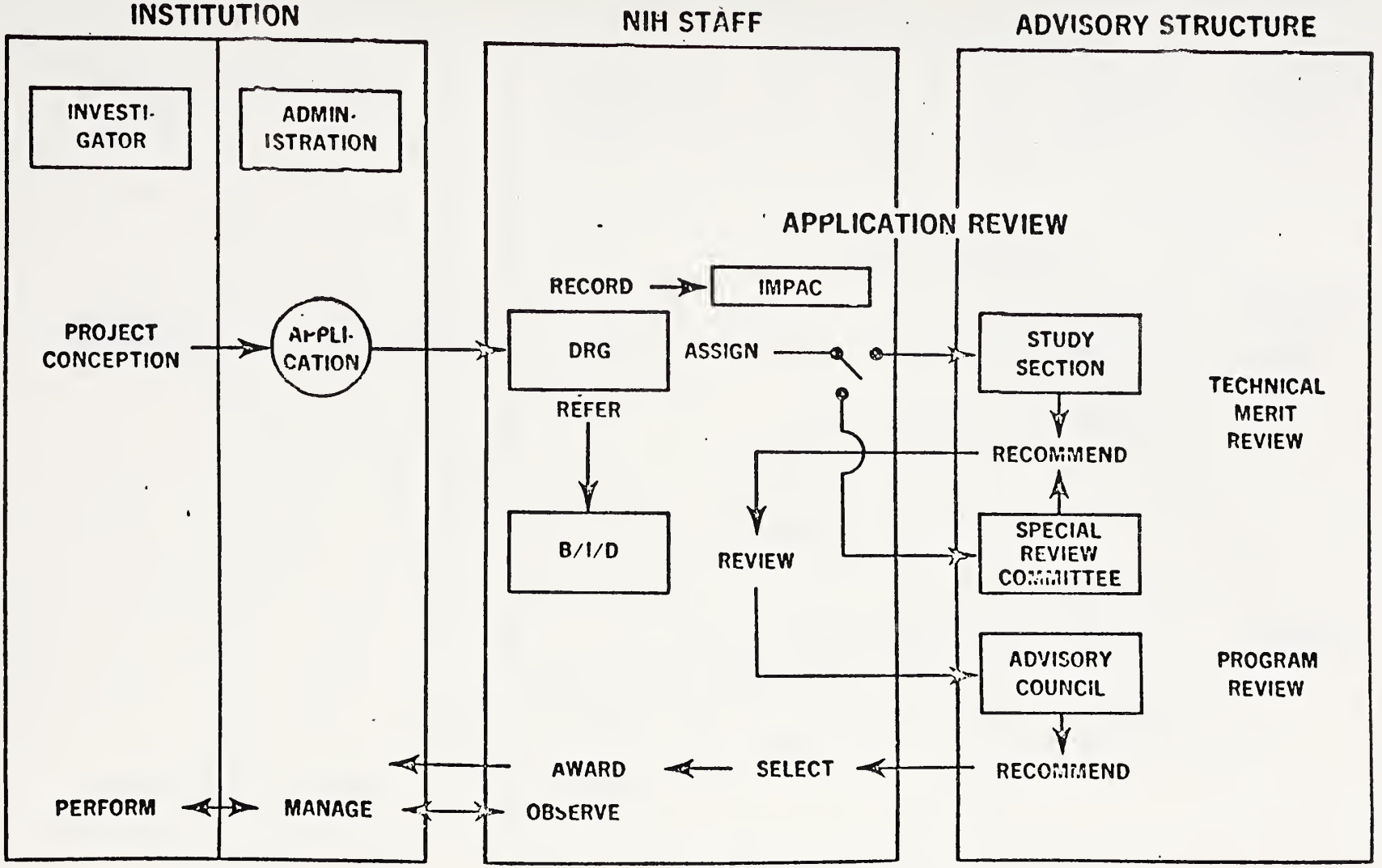
4. On balance, these trends appear to auger well for biomedical research.

5. It is clear, though, that continued support cannot be expected unless the people and their representatives in Congress and the administration gain a better understanding of biomedical research, its opportunities, and its limitations.

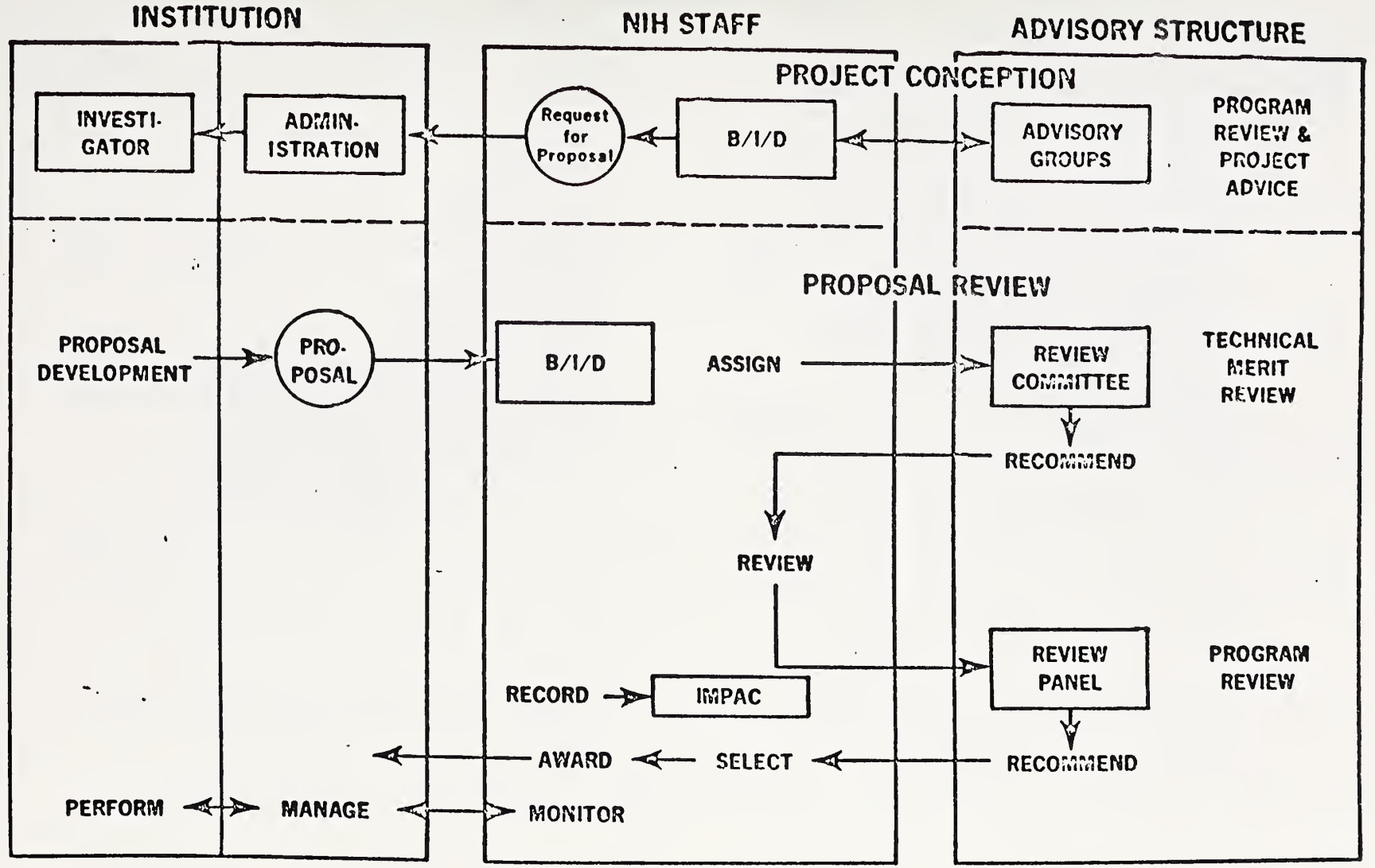
6. There should also be a stronger voice from performers as to where research opportunity lies and how funds can best be spent.

Slide 14.

REVIEW PROCESS FOR NIH EXTRAMURAL AWARDS - GRANTS



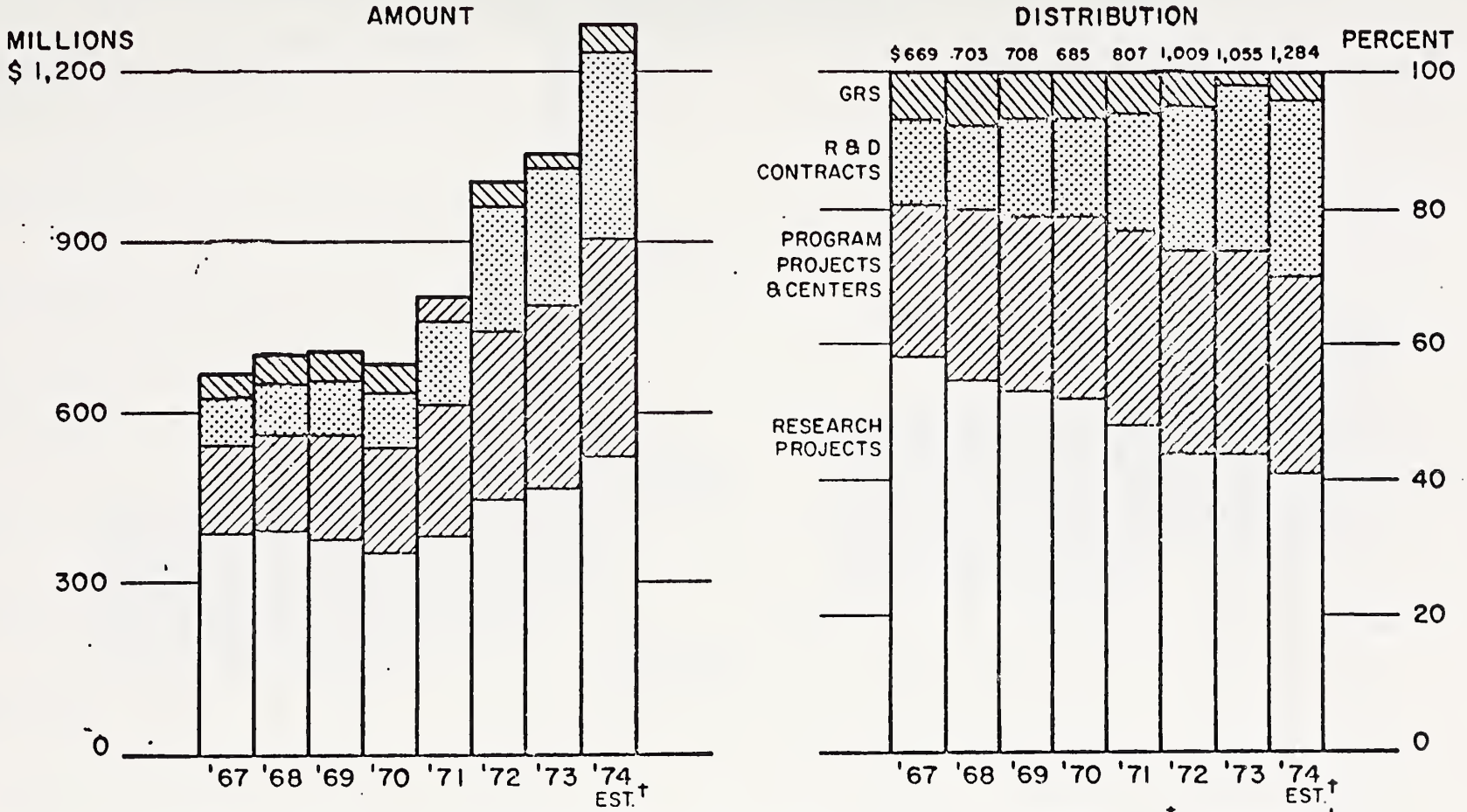
REVIEW PROCESS FOR NIH EXTRAMURAL AWARDS - CONTRACTS



Slide 16.

NIH EXTRAMURAL RESEARCH PROGRAM AWARDS AND THEIR PERCENT DISTRIBUTION*

FISCAL YEARS 1967 – 1974 EST.

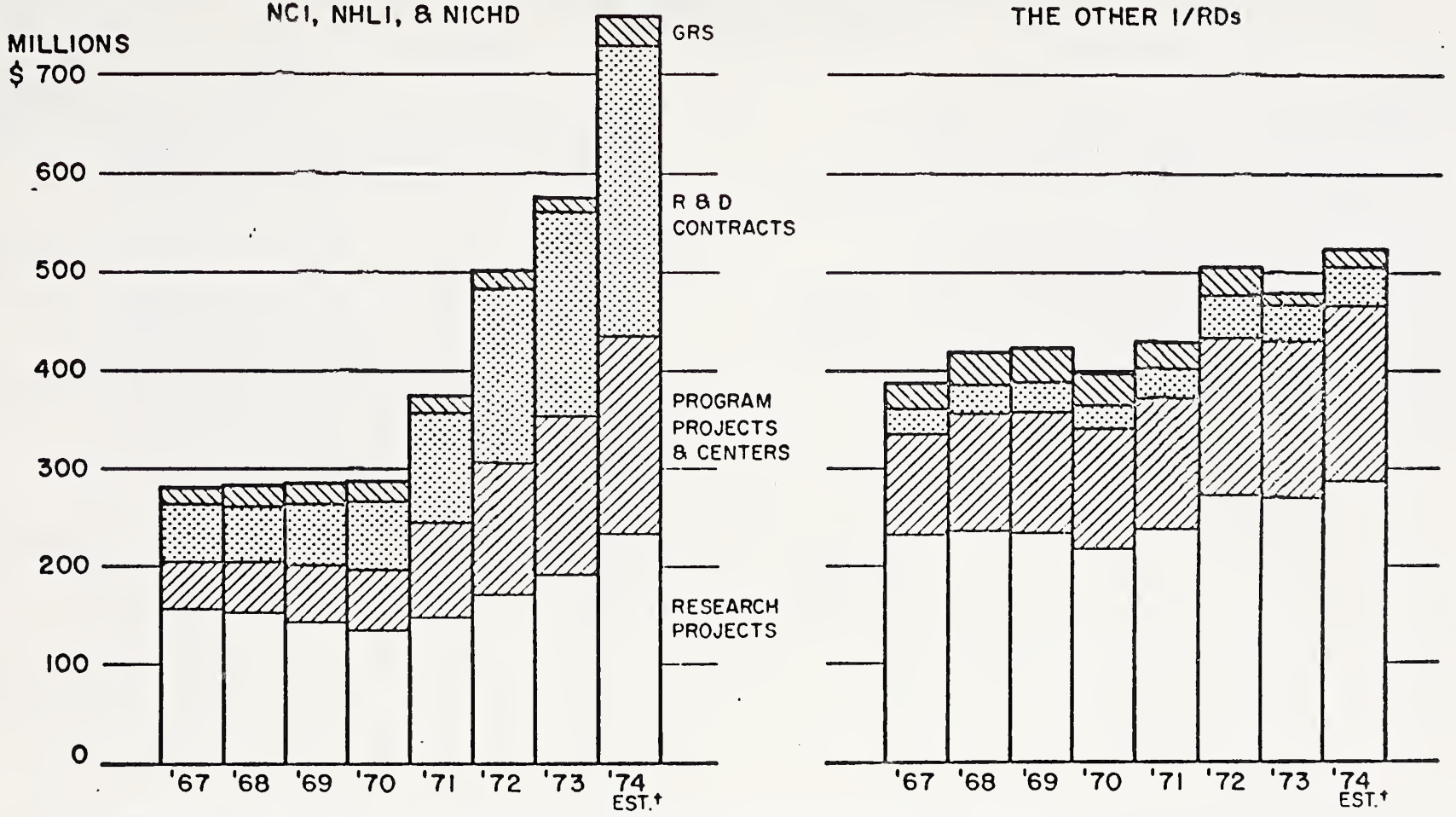


*INCLUDES I/RDs ONLY. EXCLUDES NIMH (AND NIMH PORTION OF GRS PROGRAMS). †EXCLUDES $160 MILLION WITHHELD IN FY 1973 AND RELEASED IN FY 1974.

Slide 17.

NIH EXTRAMURAL RESEARCH PROGRAM AWARDS BY GROUPED INSTITUTES*

FISCAL YEARS 1967–1974 EST.

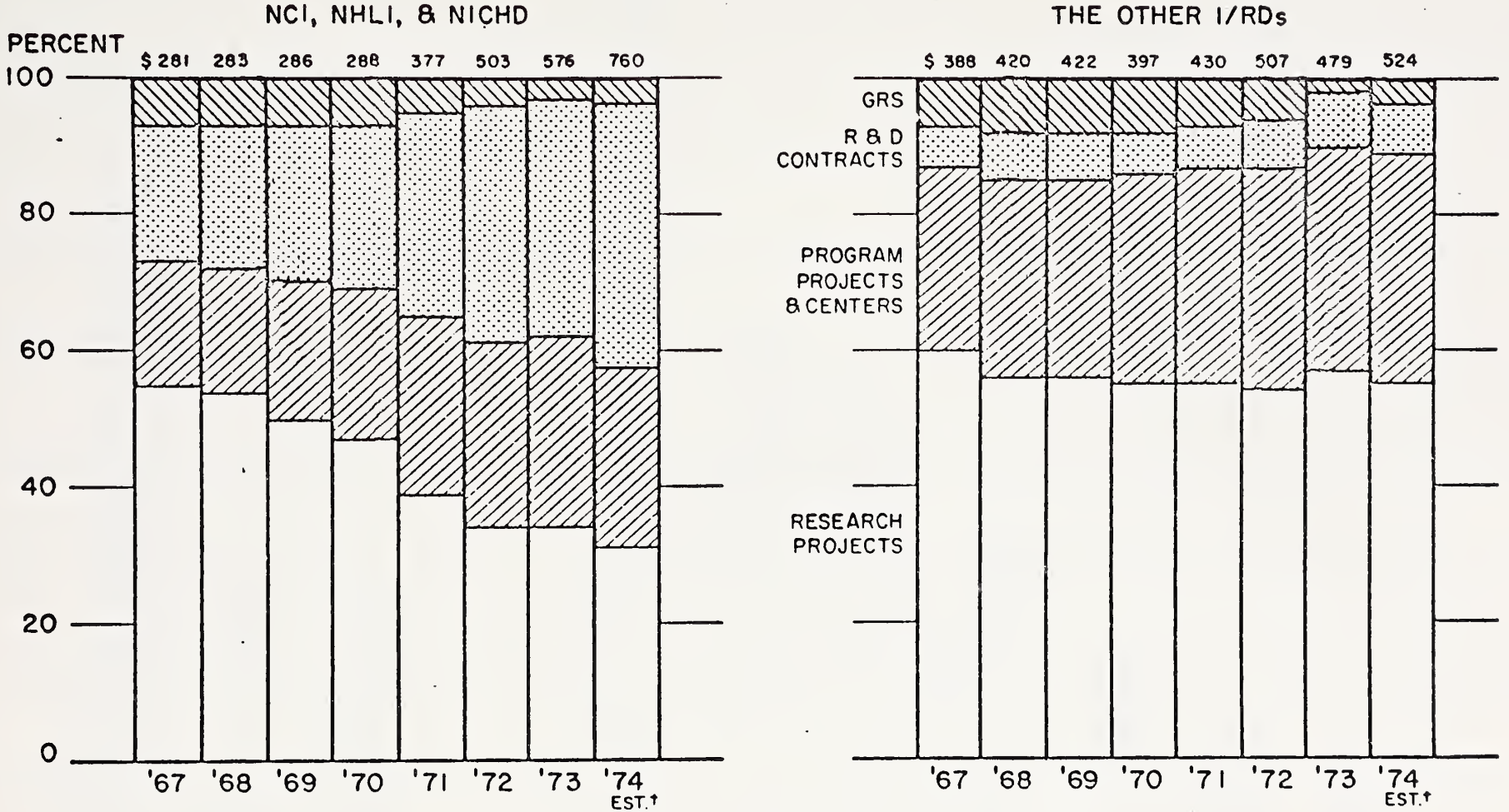


* INCLUDES I/RDs ONLY. EXCLUDES NIMH (AND NIMH PORTION OF GRS PROGRAM).
† EXCLUDES FUNDS WITHHELD IN FY 1973 AND RELEASED FOR USE IN FY 1974.

Slide 18.

PERCENTAGE DISTRIBUTION OF NIH EXTRAMURAL RESEARCH PROGRAM AWARDS* BY GROUPED INSTITUTES, FISCAL YEARS 1967 - 1974 EST.

(DOLLARS IN MILLIONS)



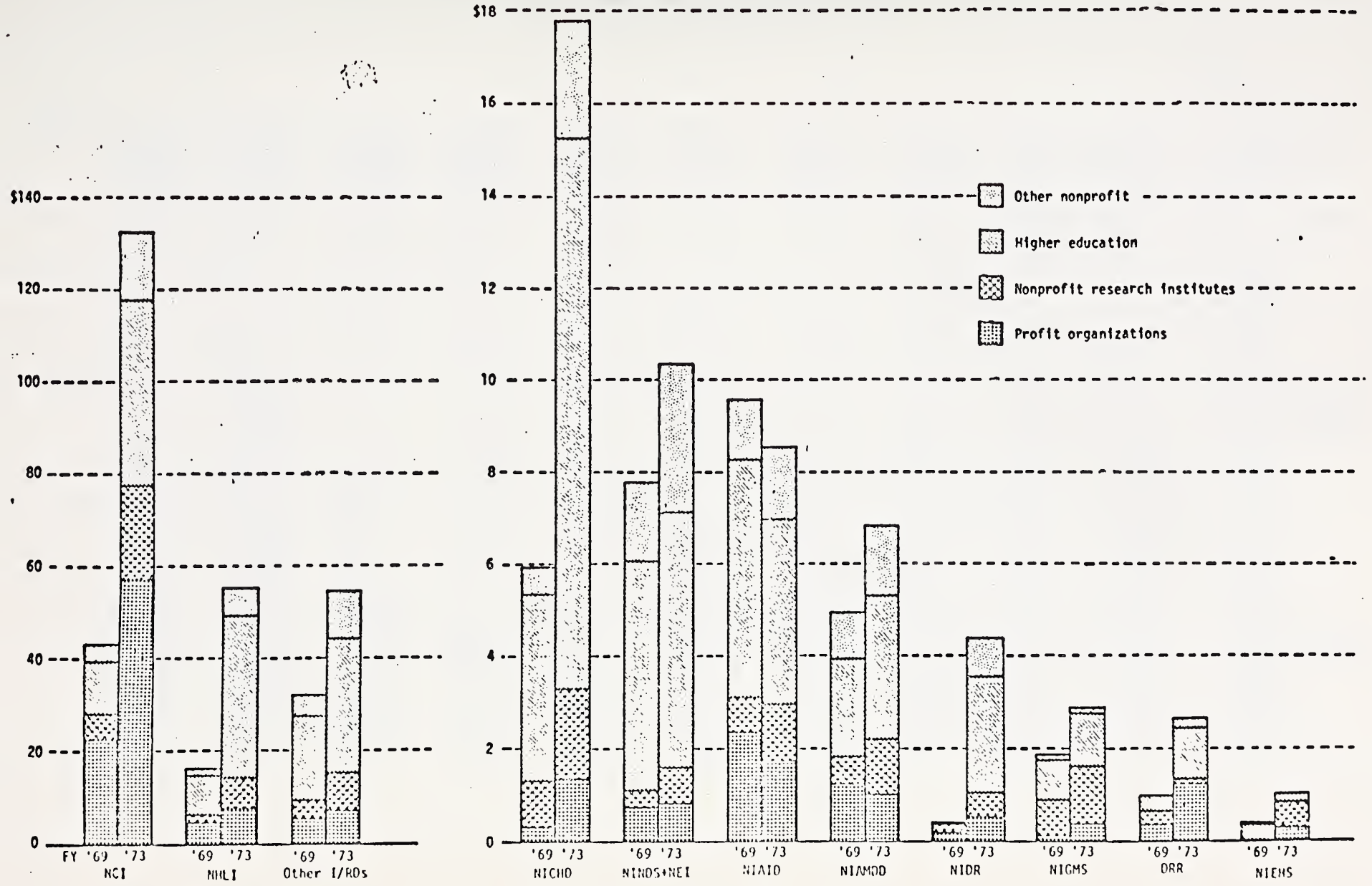
* INCLUDES I/RDs ONLY. EXCLUDES NIMH (AND NIMH PORTION OF GRS PROGRAM).

† EXCLUDES FUNDS WITHHELD IN FY 1973 AND RELEASED FOR USE IN FY 1974.

Slide 1

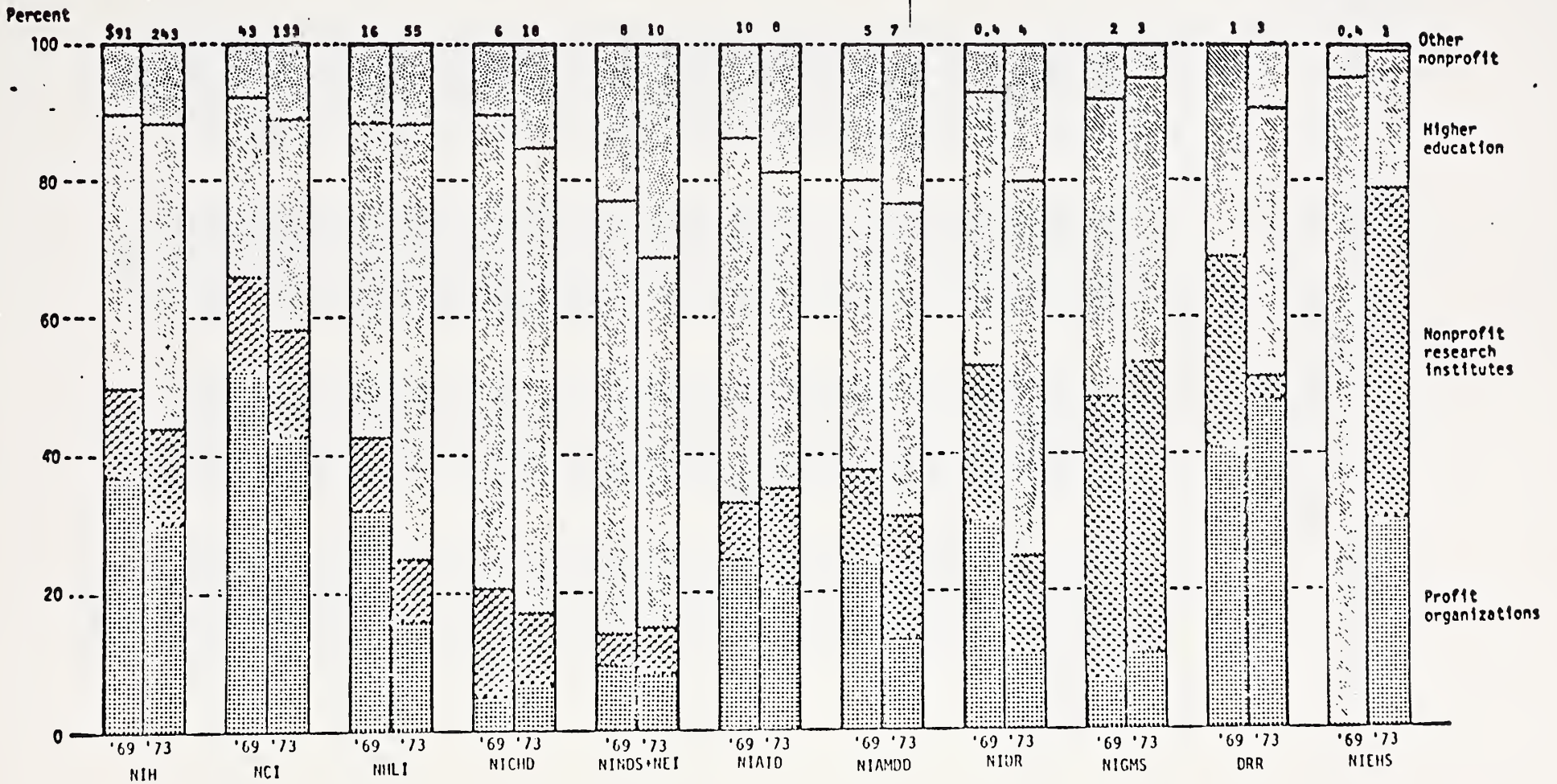
NIH R & D CONTRACTS BY INSTITUTE AND PERFORMER, FISCAL YEARS 1969 & 1973

(In Millions of Dollars)



Slide 20.

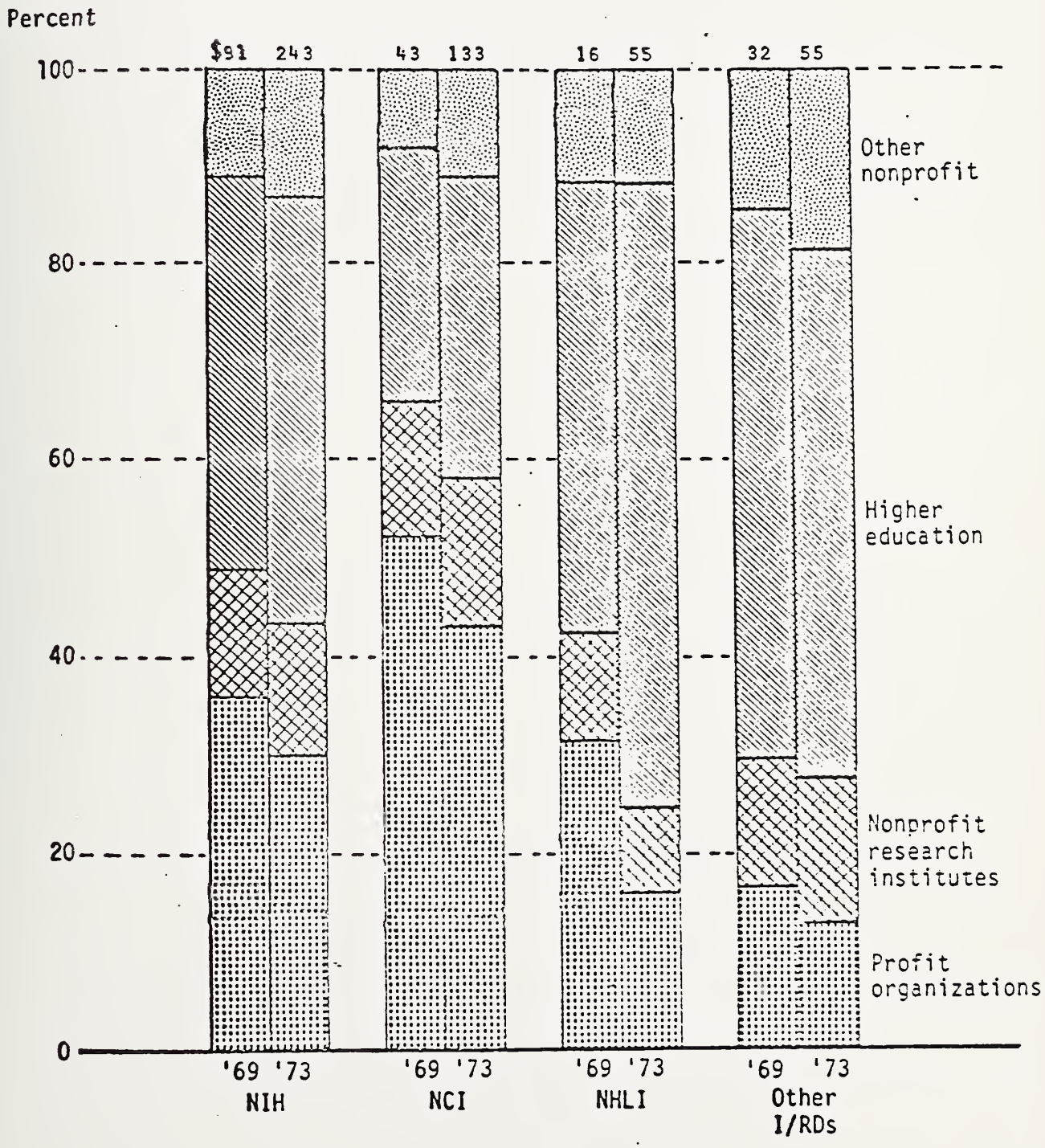
PERCENTAGE DISTRIBUTION OF NIH R & D CONTRACTS BY INSTITUTE
AND PERFORMER, FISCAL YEARS 1969 & 1973
(DOLLARS IN MILLIONS)



Slide 21.

PERCENTAGE DISTRIBUTION OF NIH R & D CONTRACTS BY SELECTED INSTITUTES AND PERFORMER, FISCAL YEARS 1969 & 1973

(DOLLARS IN MILLIONS)



TAB 12

SOME COMMENTS ON THE BASES FOR INITIATING, PLANNING AND MANAGING R & D PROGRAMS IN THE BIOMEDICAL SCIENCES*

Robert S. Stone, M.D.**

The Complexity of Modern Institutions

Contemporary institutions, if they consist of more than a small number of individuals and command fiscal resources large by single-person standards, have evolved into highly complex organizations. Size in itself has not been the critical factor in the evolution of our institutions into such complexity that their very "manageability" is called into question. Instead, much more of the change can be attributed to the pluralism in management which has become absolutely essential for reasons we will look at briefly in examining the decision-making process.

A simple organizational model composed of a hierarchy with a number of clearly accountable levels of responsibility--the classical bureaucracy, for example--is no longer an adequate conceptual guide for managers. Neither decision-making nor information flow conforms with the most familiar table of organization. The effectiveness of the manager who believes in the simple model is likely to be impaired, whether or not he adjusts partially to the realities. Dissonance between

*Gus Carroll Memorial Lecture, AAMC's Annual Meeting, Chicago, Ill., 11/11/74.

**Director, National Institutes of Health, U.S. Dept. of Health, Education, and Welfare, Bethesda, Maryland.

model and reality will make for poor decisions and poor relations with co-workers.

Today the needs imposed by the environment in which the organization is immersed are so diverse that many different competencies must be available if the organization is to stay alive. That is to say, just the body of knowledge, information and skills required for organizational survival is vastly greater than it was in the days when a simple bureaucratic structure was appropriate. Furthermore, our contemporary society has placed new value upon individual worth and has a new understanding that the best that is in people is only forthcoming when contributed voluntarily. These factors have converted the internal milieu of the organization into a multidimensional, protean network of relationships among human beings which we have only a limited capacity to represent graphically.

All managers of experience can describe such networks operating within their own areas of responsibility above, below, and lateral to them. They will usually certify that the network has active or less active pathways depending upon such variables as the particular problem being addressed, the time of day, who happens to be in or out of town, ego needs of those involved, past history, the formal organizational structure, and manifold other subtle and not-so-subtle factors.

Behavioral science as applied to management has convinced many that employees give their best to the life of an organization when they most feel a part of it. This quality of belonging is strongly related to

the opportunity to exercise judgment and contribute thoughts and ideas. In other words, people must believe they are a part of what has been characterized as the organization's power structure or decision-making apparatus. Today's most effective managers recognize and act as if decision-making must prevail throughout all levels of a healthy organization. Furthermore, they believe that explicit acknowledgment and respect for this requirement strengthen the organization in accomplishing its mission.

This understanding must be joined with a comprehension of the high volume, velocity, and complexity of information flow which large modern organizations require. Failure to insist on this can result in a deleterious abdication rather than delegation of responsibility.

Moreover, we must be constantly alert to the time cost in accomplishing particular tasks. "Time cost" here is total time required to develop concurrence by a number of persons whose joint effort must be applied to the desired end. Autocratic or oligarchic, top-down direction facilitates some tasks and appears to be highly efficient in the short run. However, the saving of time in the short run might be very costly over the long term if it results in the loss of personal commitment of valuable individuals to organizational goals.

One further observation on complexity: No unit within a complex organization can work with total dedication to its own goals because it must concomitantly devote part of its effort to support other units. Conversely, it can accomplish its mission only at some expense to those companion units. In practice, then, short-run effectiveness must be traded off against longer-term costs for the total organization.

The reason behind this lies, of course, in the absolute limitation on total resources available and the costliness of maintaining slack resources to be mobilized only in emergencies.

Needs of Health Organizations

In the absence of objective information, it would be hazardous to claim that organizations in the health field have an exceptional requirement for diffusion of decision-making and for individual autonomy. It does appear, though, that the need for both individual autonomy and interdependence within such organizations--those engaged in health care, health education, and health research--is relatively high. This requirement is probably due in part to the intellectual nature of the tasks undertaken, to subcultural norms, and to the high level of uncertainty surrounding the substantive problems of how to foster human health. The academic traditions of many of the organizations involved in health matters also contribute to the demand for individual autonomy and the acceptance of varying degrees of interdependency.

Health organizations seem to be giving increasing recognition to the role of teams--groups of individuals banded together to accomplish particular tasks, sometimes with varying leadership dependent upon immediate needs. This recognition is more and more explicit and influential in the administration of patient care. The fact is that teams are at work not only in direct patient care but throughout the general management of health organizations. Appreciation and application of this concept is, in my view, essential at the uppermost

level of the organization where the functions of diverse subunits must be integrated.

Planning and Management in the Academic Medical Center

The leadership of academic medical centers and their associated institutions increasingly recognizes that literally innumerable subsystems--clinical care, financial management, personnel management, physical maintenance, purchasing, academic leadership itself--must be closely coupled, and must reciprocate in diverse tasks. The effect of economic factors in constraining resources heightens the necessity.

In the multiple missions of the academic health center, each member of the top management must add to his specialized functions--whether in academic affairs, financial matters, or personnel management--a generalist's understanding and approach. It is dangerous to organizational health to describe the center's mission in such restrictive terms as the education of medical students, the production of new knowledge, or the delivery of optimal patient care. Instead, all of these missions coexist, and indeed overtly and covertly compete with each other for limited resources. No single mission achieves absolute priority for any extended time, and each, in fact, must contribute to the accomplishment of the others' goals.

The financial staff of the institution, for example, needs some understanding of the environment of laboratory research, not only in order to meet regular budgetary needs for supplies and equipment but sometimes to rapidly accommodate to new-found opportunity. Rules for the procurement of supplies are selectively and responsively broadened

by the understanding supply officer or financial manager. On the other hand, the clinician must learn to distinguish between his real needs related to promptness and urgency in patient care and the impositions he might tend to place on others through impatience, insensitivity, or his own lack of foresight.

The day of the accountant as business officer, or the green-eyeshade syndrome, is behind us. The several external environments now facing subsystems within the medical center demand that each member of the top management team understands the important academic issues within each overlapping subsystem in the institution--for instance, discipline-based vs. integrated curricula, the trade-offs in quality of personal health care as between health maintenance organizations and traditional practice, and prejudices of scientists or administrators relating to contract-vs.-grant support of research. Knowledge and skills limited to purely financial matters, important as these are to the business officer's job, are insufficient for a full, thoughtful and creative role in resource allocation and policy formulation.

Holding these beliefs to have wide applicability, I have no compunction about using this particular forum for a discussion of some general management issues and, more specifically, of issues related to the planning and management of biomedical research. I expect that such matters will not only be of interest, but that the development of informed viewpoints about them is an obligation of full citizenship within the medical center.

Planning and Management in Biomedical Science

Just as the bureaucratic organizational model is inadequate for structuring relationships among people, so also are the somewhat implicit models for planning and management which many inappropriately apply to biomedical science. They are often overly limited in concept and incongruous with the real state of affairs.

A concept of planning as an activity performed at some higher tier and directed downward--planning intended to regulate the activities of others in the pursuit of one's own aims--rightly arouses the ire of those who see themselves as subjects. Because of strong beliefs regarding the intrinsic logic and momentum of research, the scientist is particularly opposed to managerial direction. If the manager's and the scientist's concepts of management emanate from what each believes goes on in corporate structures, in the church, or in the military, one or the other will surely be frustrated, resentful or rebellious. Similarly, if those who are responsible for allocating resources entertain simplistic engineering-process models of the scientific research process, their successes are likely to be extremely short-lived, if they occur at all. They will be accomplished only at substantial cost when viewed over a longer time.

The Problem of Allocation

One of my purposes this afternoon is to consider with you the observation that historically rooted views of both planning and management as being either authoritarian and bureaucratic or entrepreneurial and laissez-faire are inappropriate for biomedical research,

and indeed for the academic medical center. There are other, more realistic models available which can serve the needs of those who demand to see thoughtful, deliberate planning and management in order to feel comfortable about the allocation of limited biomedical-research and health resources.

In the first place, planning and management, with their consequent allocation and dispersal of resources, are inevitably hierarchical and cascading processes, even in matrix organizations where hierarchy is partially reduced and less evident. The decision to allocate $2 billion of the Federal budget to biomedical research is a planned decision made pluralistically in the face of innumerable determinants, including special-interest demands, competing needs, history, dread of disease, semiquantitative analyses relative to the social cost of various illnesses, and rather poorly understood or perceived scientific opportunity. There is actually no objective basis for the decision that $2 billion is the proper proportion of total Federal resources to be allocated to biomedical research in 1975. The allocation, nevertheless, results from a planning process.

Those of us involved in the evaluation of scientific opportunities as seen from the viewpoint of research administration, or in estimating the fiscal burden of illness, might regard $2 billion as grossly inadequate. On the other hand, we are unable to calculate the social cost of unexploited opportunities within other broad social or publicly shared missions, whose protagonists can also regard their share of the pie as arbitrary and insufficient. Yet given our political system, we may legitimately contend that biomedical research is more important

than space exploration, national parks, the national defense, education, and so forth. Additionally, as citizens with general knowledge about our country, and special knowledge of opportunities and needs in the health field, we are free to register through the political process--indeed, are obligated to do so vigorously--our opinions about relative priorities of items on the national agenda.

Few are naive enough to believe that competition for resources at this semi-macro level--that is, at the budgeting level where the total amount to be assigned to biomedical research is determined--is not politically determined. Political, in this sense, means that the decision is made in a pluralistic, democratic society with all its strengths and imperfections. The decisions are not made on the basis of pure reason because, in fact, pure reason provides no irrefutable basis for the allocation of limited resources, and they are not developed within the logic of a single intellect.

As I have indicated, the process nevertheless involves planning, in the sense that a plan is simply a prospective schema for action. The process which suballocates from the aggregate of $2 billion a certain sum to each of the several Institutes of Health is subject to the same theoretical constraints as the larger allocation. If the National Institute of Arthritis, Metabolism, and Digestive Diseases is assigned a budget of, say, $140 million, a substantial portion of which is already committed to ongoing projects, how much of the newly available marginal dollar should be applied to research on diabetes, arthritis, or renal disease? One might say that such an allocation should be made on the basis of scientific opportunity. Is there a basis, however, for

deciding that a good research proposal (as judged by a peer review group) related to diabetes mellitus is more worthy of support than one also adjudged good in arthritis or genetics or, for that matter, in molecular biology without reference to any specific disease? In the jargon of the planner, they are "incommensurable" items. The best we can offer, and it should not be denigrated, is informed judgment and some semblance of a consensus.

A substantial part of the allocation problem, of course, is contained in the fact that the field of biomedical science, or of strategies to foster health generally, are so broad that there are few persons if any with the capability to sight across them and select targets of opportunity that, looked at ten or twenty years from now, might be judged as wisely chosen. Note that even an allocation of the total $2 billion for biomedical research, if based entirely on peer-group evaluations of scientific merit, would still not settle the question of how to choose among projects all regarded as equally meritorious but all competing for limited resources.

Therefore, planning at various levels of aggregation on some mixed basis of fact and speculation is unquestionably necessary. The subsidiary and dependent questions are, Who does the planning? for whom? and to what fine-structure level within the substance of science? If we have in mind only the two models of planning for research--that is, awarding an unrestricted sum of money to an individual to use with quite wide discretion or, on the other hand, contracting for a certain specific, measurable outcome--we will be unable to have a useful discussion about assignment of resources. If, however, we consider

other models between these extremes, we can begin to accept the idea that multiple models are realistic, necessary and inevitable. We can turn our energies from acrimonious and futile debate about issues of "balance"--as between, say, contract and grant support, basic and applied research, cancer and other health problems, individual investigator and program project. We can look analytically at the scientific substance and evolutionary state of the problem that needs solving, and we can employ the best collective judgment available in deciding what mix of tools or dimensions for planning and management are most appropriate.

The remainder of my talk will be given to some comments about the process of fund allocation in respect to health research programs, and the selection of research and funding approaches between the extremes of laissez-faire and objective-oriented support. To illustrate these practices, I will mention current NIH programs, though it should be made clear that the characterizations--"high-scientific, low-immediate-social justification," etc.--are only relative: all the illustrative programs have won out over innumerable other possibilities.

The various models for planning and management can be judiciously applied not only in accordance with the intrinsic needs of scientific discovery, but in fact so as actually to facilitate scientific problem-solving. In a general way they represent a spectrum from the very informal requirements for the most basic studies to the formal, more structured systems conducive to direct social utility. In practice, so many different dimensions or tools are available that the intermediate

models on the planning/management continuum are as often employed as those at the poles.

We shall look now at planning and management only as regards the rationale and mechanism of funding. NIH uses many other tools or dimensions for management which we will not discuss. In reality, allocation of biomedical research funds is a complex, multifactorial process. Except for limited programs of general research support, it follows no formulas. This is not to say, however, that it cannot be analyzed and even depicted in graphic terms.

The first figure lists NIH programs chosen from among many possibilities to illustrate certain points. The institutional locus, starting year, and fiscal 1975 funding level are shown.

Figure 2 represents the main factors of allocation--the scientific and social. Both dimensions comprise many forces or vectors, of which major ones are indicated.

The interplay of scientific and social determinants of allocation is illustrated in figure 3. Here the two axes are scaled, paralleling the NIH priority-score system--scores 1 to 5 denoting high to low. The shaded portion represents available funds sufficient to support half of the worthy proposals, assuming an even scatter of potential costs. Three of the programs on the above list are shown as funded, with A having a composite score of 4/1; B, of about 2.5/2.5; and C, of 1/4. Only if sufficient funds were available to encompass program X--relatively low on both scales--would it be supported.

Figure 4 illustrates, in a highly figurative way, how weighting of the variables occurs in practice as scientific considerations or social pressures bear upon the programs in progress and proposed. In the first panel, the tilt is toward science--that is, fewer programs or projects of low scientific potential are funded. Presumably, program A, sudden infant deaths, would lose out. Others (not shown) in this category might be acupuncture or sickle cell anemia. In the second panel, the tilt is toward the social. Program C, the chenodeoxycholic acid treatment of cholesterol gallstones, with high scientific potential but little glamor, would be omitted in favor of A.

Figure 5 illustrates an axiom of biomedical research programming--that the adequacy of the science base, or available knowledge, in a given area should determine whether to emphasize basic, applied or developmental research. A parallel axis is the type of support, ranging from unstructured or laissez-faire to programmed or targeted. Program D, aging studies, has yielded to date a limited science base and calls for continued emphasis on basic research supported through investigator-initiated projects. Program E, genetics centers, has an adequate science base to permit promising ventures in such applied research areas as amniocentesis, genetics counseling, and chemotherapy. The preventive medicine program, F, can be largely developmental, as it draws upon a substantial reservoir of fact.

Mechanisms for Review and Funding

Assume that the forces in play have dictated the allocation, that the research program has been designed, and that the task at hand is

to choose the funding instrument. Figure 6 offers criteria for selecting the grant or the contract. Program G, the cancer organ cite study, would meet all these criteria for a grant; whereas B, the cancer virus program, calls for contract support.

It will be seen from these criteria that the grant, as shown in figure 7, would be preferable as a rule for supporting fundamental research; the contract, for development. Either might be chosen for applied research.

There are no rigid rules, but projects supported under the two devices tend to present contrasting characteristics, as we see in the figure 8. To draw again from our list, the characteristics on the left largely suit program H, heart centers for research and demonstration, while those on the right suit several projects in J, our laboratory of vironeurobiology. Many programs such as I, the national caries program, have both sets of attributes and are financed both ways.

Figures 9 and 10 illustrate similarities and differences between grant and contract review mechanisms. The part above the dotted line in 10 is unique to contracts, in that it represents the flow of ideas from NIH toward the investigator. Below that point, there is little difference between this process and the previous one, except that the advisory structure is partly intramural. The advisory groups for contracts range from ad hoc to chartered, from five or six members to about two dozen, and from all staff to all extramural--but care is exercised to maintain objectivity as the proposal moves from

intramural conception to contractor formulation and back for review and selection. Later monitoring of performance is an active staff role.

Applicability of Contingency Theory

I should like to conclude with some considerations for bioscience administration within the framework of management contingency theory. The theory holds that the choices of organizational structure and management techniques taken generally should be contingent upon salient characteristics of the immediate environment and the problem to be solved. Figure 11 broadens this concept to include other variables, such as the public interest as a seminal force and the application of results--say, through control programs--as an extended function of the institution.

It will be seen that independent/dependent are relative terms in this context. For example, statutory mission may depend upon public interest, but once established, it becomes a constant governing program development. You will also note that a one-to-one alignment is not intended: many factors besides institutional quality, for instance, will determine results.

Application of results is a recently strengthened mission for the National Cancer Institute. Not yet clear is the extent to which mission broadening will occur in other programmatic areas through added resources or the reallocation of existing ones.

The figure reflects the fluid state of program administration in a viable modern organization, and emphasizes the point that problem-solving must be viewed as having multiple approaches. NIH, in common

with many other social institutions, is developing tools and systems for dealing with contemporary problems through changing concepts of organization and enhanced understanding of pluralistic management.

Figure 1.

SOME CURRENT NIH PROGRAMS ILLUSTRATING DIVERSE MANAGEMENT TECHNIQUES

Program	Institute	Started	'75 funding (in millions)
A. Sudden infant deaths	NICHD	1971	$ 5
B. Cancer virus program	NCI	1964	50
C. Chenodeoxycholic acid study	NIAMDD	1973	1
D. Aging studies	NIA	1974	14
E. Genetics centers	NIGMS	1971	5
F. Preventive medicine	FIC	1971	0.2
G. Cancer organ site study	NCI	1972	15
H. Heart res. and demon.	NHLI	1972	5
I. National caries program	NIDR	1971	7
J. Lab. of vironeurobiology	NINDS	1962	2
K. U.S. -Japan med. sci. program	NIAID	1965	7
L. Sickle cell disease	NHLI	1971	16
M. Fogarty scholars program	FIC	1969	0.3

Figure 2.

THE TWO MAIN AXES OF ALLOCATION, WITH SOME MAJOR VECTORS

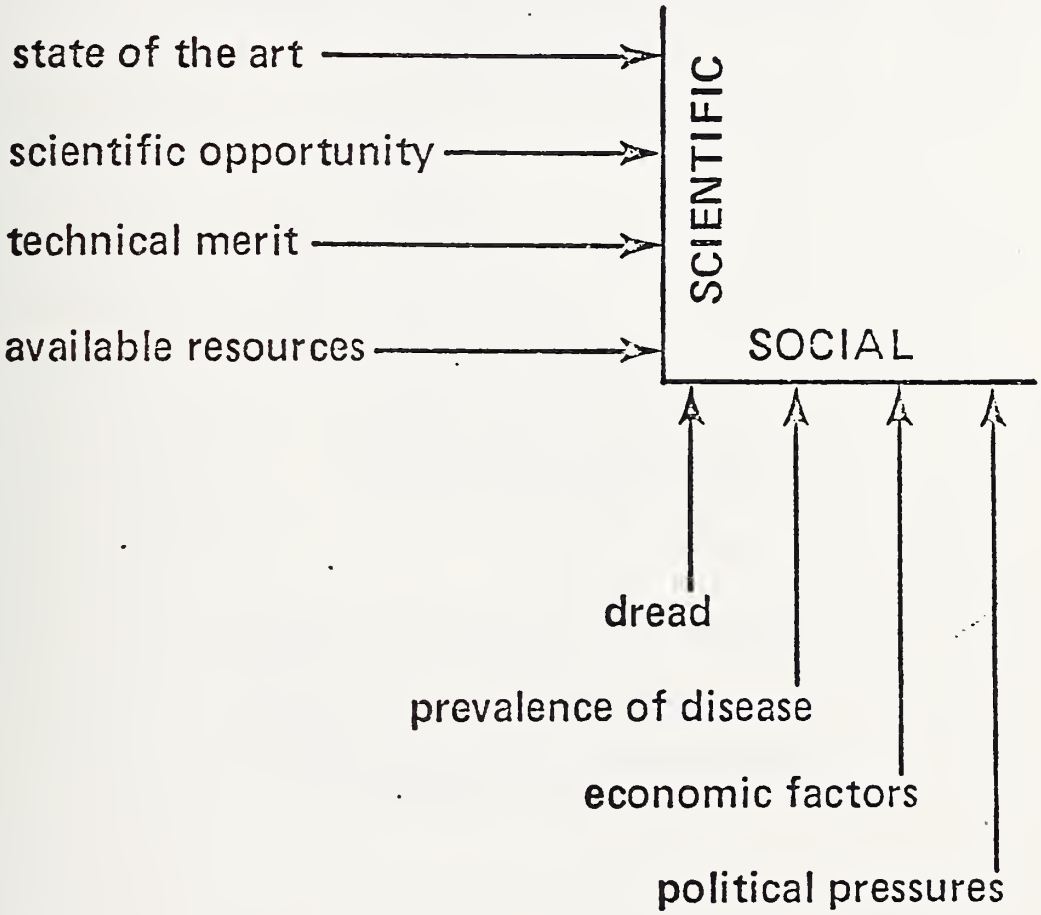
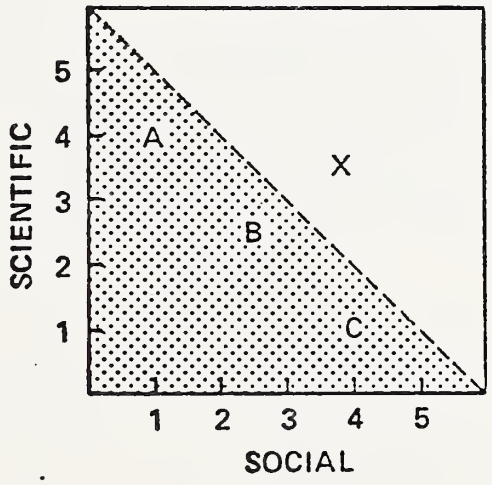


Figure 3.

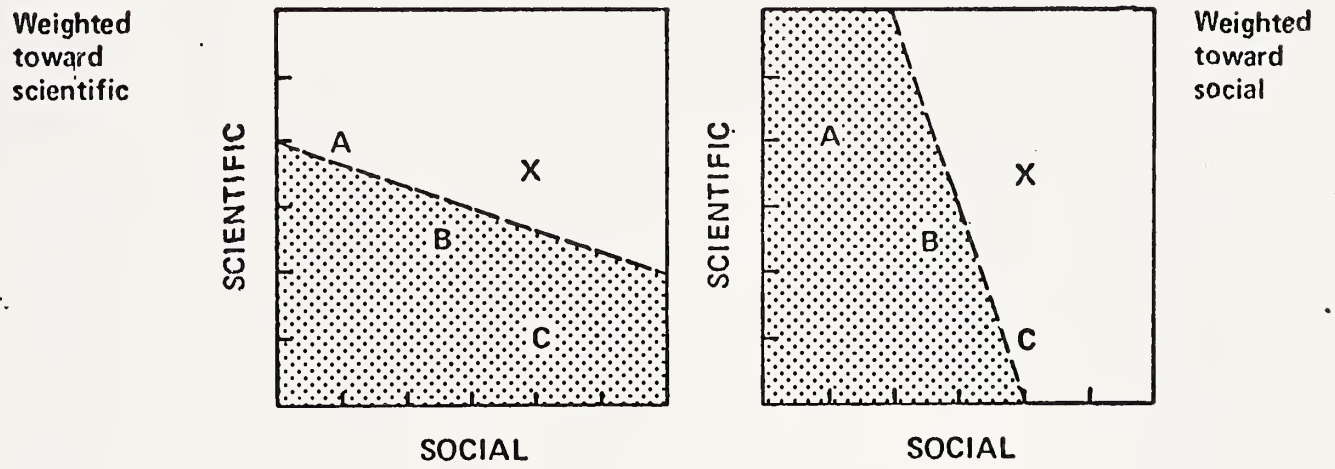
PROGRAM ASSESSMENTS AND ALLOCATION
(FIGURATIVE)
(1 → 5 = high → low)



- Total area = cost of all worthy proposals.
- Shaded area = funds available.
- Proposals A,B and C are funded, X is not.
- Slope of dotted line = weighting of scientific vs. social determinants.

Figure 4.

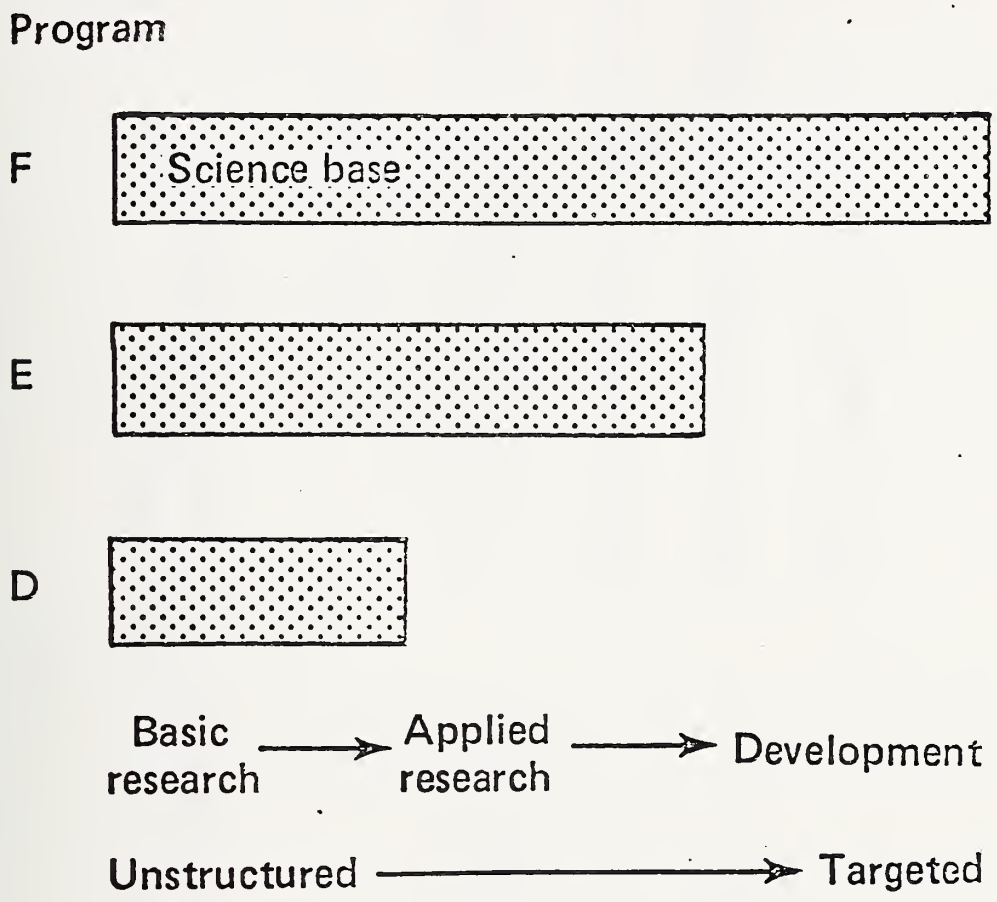
ALLOCATION STRESSING SCIENTIFIC
OR SOCIAL DETERMINANTS
(1 → 5 = high → low)



- 50% funding under both policies.
- Alternate rejection/acceptance of programs A and C.

Figure 5.

ADEQUACY OF SCIENCE BASE AS DETERMINANT OF R & D APPROACH



- Program D has inadequate science base; further basic research indicated.
- E and F permit higher degrees of programmed effort.
- In general, unstructured support is appropriate to basic research; targeted, or goal-oriented, to development.

Figure 6.

GRANT OR CONTRACT?
Criteria for Determining Instrument of Choice

Grant	*Contract*
Project conceived by investigator	Project conceived by NIH
NIH supports or assists	NIH procures service or product
Performer defines details and retains scientific freedom	NIH exercises direction or control
NIH maintains cognizance	NIH closely monitors

Figure 7.

GRANT VS. CONTRACT
Type of Project Generally Supported

Grant		*Contract*
Fundamental research		Development
	Applied research	
Institutional support and training		Multi-institutional clinical trials, etc.
	Support of resources and facilities	

Figure 8.

GRANT VS. CONTRACT
Some Contrasting Project Characteristics

Grant	*Contract*
Diversified program	Targeted program
Exploratory project	Developmental project
Outcome defined but unpredictable	Outcome predictable
Extends knowledge base	Applies existing knowledge
Flexible approach	Structured approach
Simple NIH management	Intensive management
Difficult evaluation	Easy evaluation
Single institution	Multiple performers
Few people involved	Many people involved

Figure 9.

REVIEW PROCESS FOR NIH EXTRAMURAL AWARDS - GRANTS

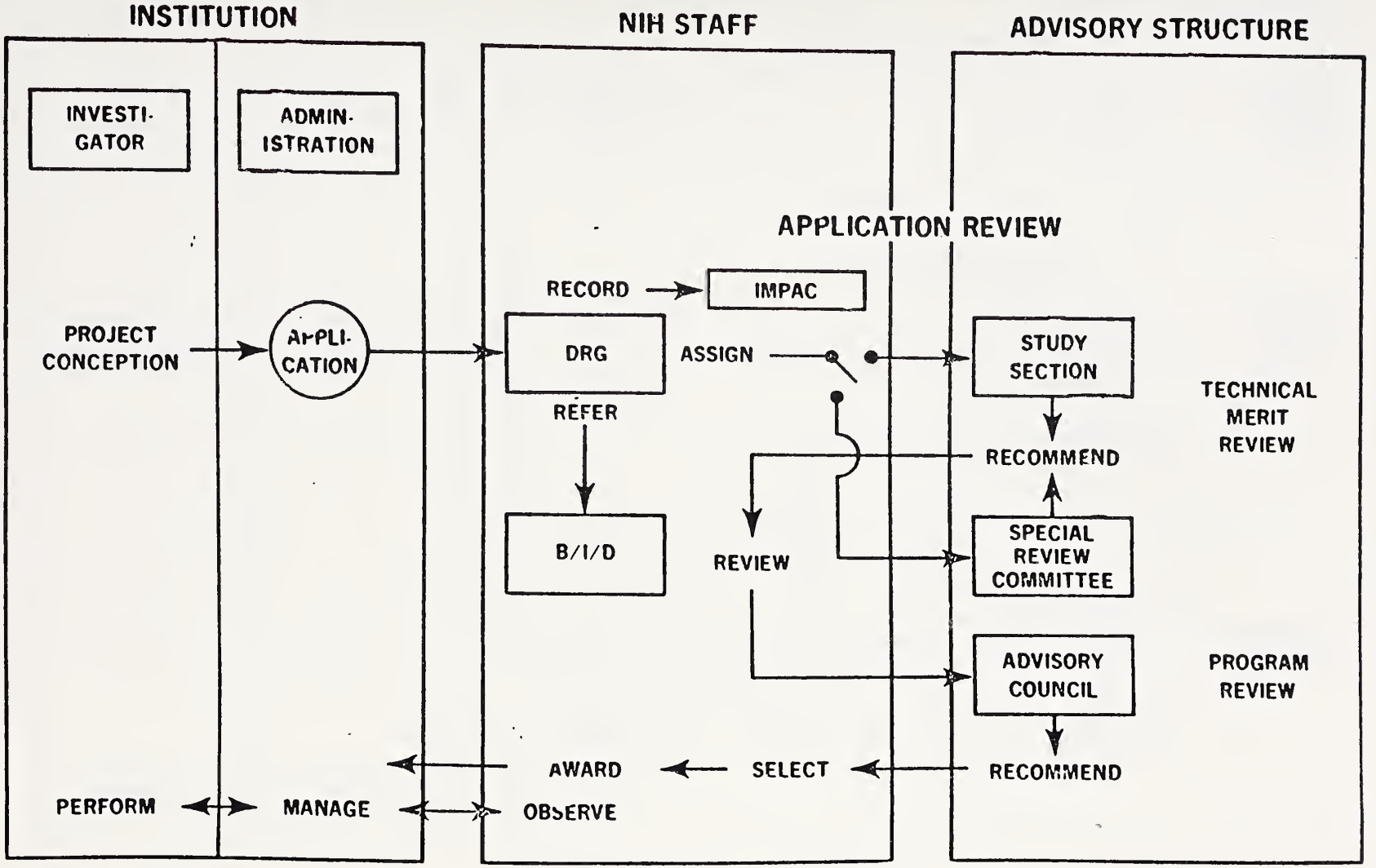


Figure 10.

REVIEW PROCESS FOR NIH EXTRAMURAL AWARDS - CONTRACTS

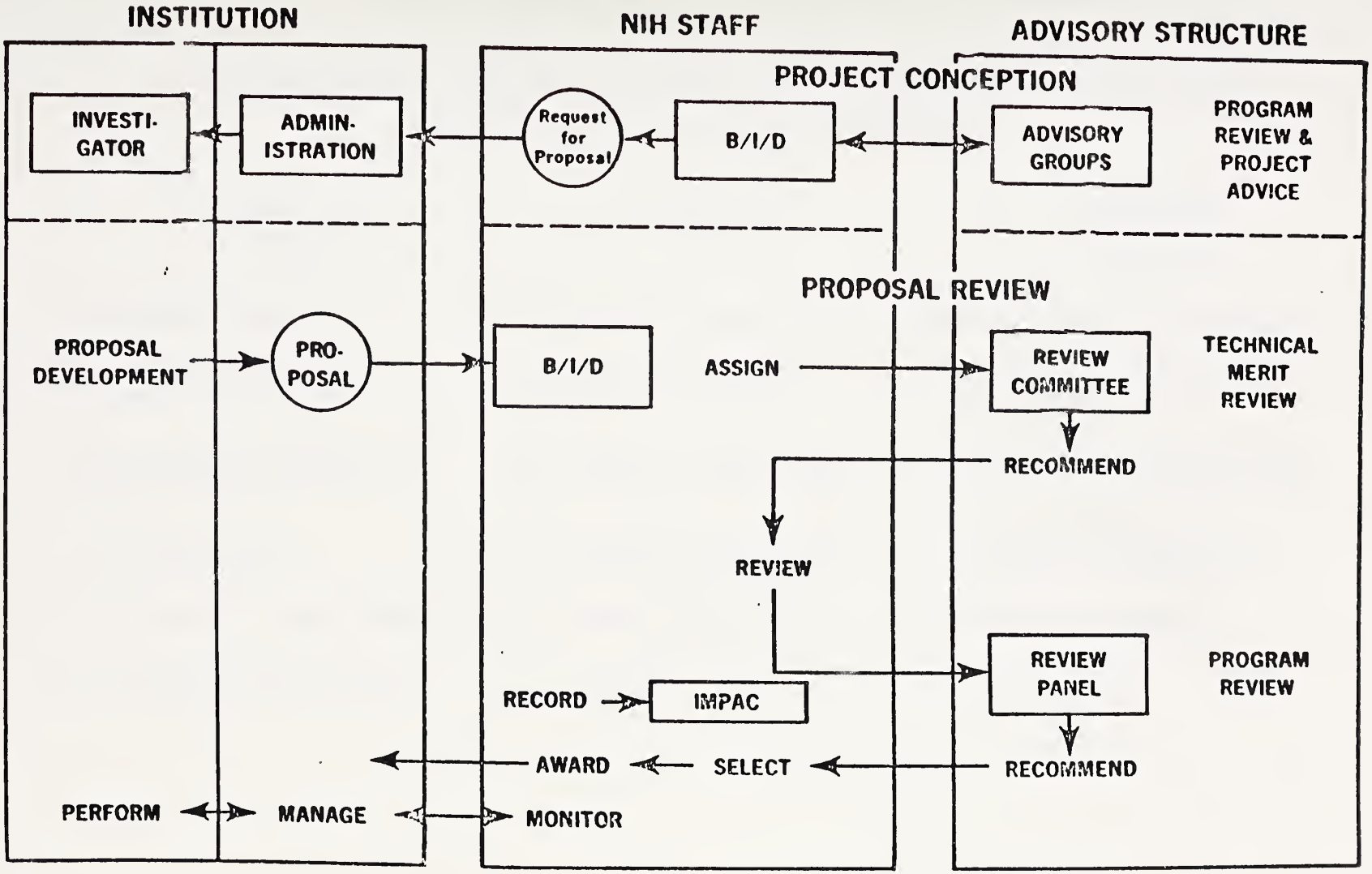


Figure 11.

CONTINGENCY THEORY AS APPLIED TO ADMINISTRATION OF A BIOMEDICAL RESEARCH PROGRAM

Independent variables	*Dependent variables*	*Dependent variables*
Public interest	Statutory mission	Program development
Institute budget	Program budget	Project allocation
Available resources	Resource allocation	Resource development
Science base	Research approach	Support mechanism
Scientific opportunity	Scientific interest	Program viability
Institutional quality	Results	Application

TAB 13

THE EVALUATION OF RESEARCH*

Robert S. Stone, M.D.

Throughout the academic medical community, there is a single point of view with respect to one aspect of Federal support of biomedical research. On most other matters some differences of opinion are expressed, but there is unanimity in the belief that uncertainty regarding the level of funding for particular programs has a profoundly unsettling and counterproductive influence. Not only is the prospective budget commonly uncertain at an overall level, but also at individual program levels; and decisions regarding any particular fiscal year are made so late that the succeeding fiscal year soon arrives with a renewal of ambiguity. Although the overall slope of support for biomedical research has continued to be positive, it is also true that distressing perturbations have occurred at the level of the individual program. Certainly with respect to specific projects, funding has often failed to keep pace with inflation, and some undesirable terminations have been required.

In general, the uncertainties have arisen as a result of substantial differences of opinion between the Administration and the Congress regarding program selection and support levels. Some of the delay is also accounted for by the Congress's customary rate of action in responding to the President's budget proposals, which are presented in January of each year.

*Prepared for delivery at the University of Missouri, March 7, 1975.

No measures exist that permit objective and quantitative evaluation of the cost of uncertainty in research funding. In any case, this cost is directly attributable to the workings of the democratic process, which in non-crisis times is distinguished by its inefficiency, though it might often be highly effective in terms of reaching decisions that have majority support. Even this last achievement, of course, is questionable because of the arcane workings of the political process; yet no superior system of government has yet been devised.

One of the beliefs widely held throughout academic medicine regarding a significant detrimental effect of our making decisions by the muddling-through method is that young men and women are finding such a climate less and less appealing in making career choices. Many of the best are electing alternate careers, no less honorable and valuable to society but a loss to the medical-science community.

Figures from some institutions suggest a diminished interest in graduate programs and in careers in research medicine. Postdoctoral enrollment in the basic sciences in American medical schools declined from 2,456 to 2,128, or 13 percent, from 1972 to '73. On the other hand, some of the finest institutions, individually, seem to be little affected. This experience might be due to their overall institutional strength, which permits survival in lean years when some of the less fit are finding existence difficult. Whether this is a desirable situation for the country is quite uncertain, and a decision about it involves many smaller judgments regarding the quality of specific programs and a capacity--not granted to any of us--to see with clarity into the future.

I have been able to gain an impressionistic view on this in several ways: from experience at NIH, from talking with individuals at many of the best research training institutions, from attending the national student research meeting in Galveston last year, from hearing reports about the minority basic medical science program meeting at Xavier University in New Orleans, and from people here during the last two days. The expressed views make me feel, if not comfortable about the future, at least not anxious. My experience here in Columbia has strongly reinforced my confidence that bright and capable young men and women in sizable number continue to elect research careers and that, at least in the foreseeable future, we can be extremely optimistic about the quality of intellect that finds challenges in research.

There is some sense of awkwardness in reaching this conclusion. It might suggest that, after all, those who have been so agitated about reduction or loss of training grants, fellowships, and the detrimental effects of indecisiveness in resource allocation have been crying wolf. It is possible that some rhetoric and hyperbole have entered the discussion. On the other hand, it might yet be too early to detect adverse trends. On balance, we might say that, in market-place terms, the values placed on a career in research medicine continue to exceed the cost in lost opportunities or income through not choosing other careers.

We might also still speculate that the excess of values over cost has diminished--that we have come to a critical point at which further diminution in the attractiveness of a research career will begin to exceed the values placed on it by larger numbers of qualified

individuals--and that defections will be far more numerous. None who have been involved in the administration and support of biomedical research would want to balance this equation too closely, particularly because deleterious effects will take some time to show up and, once begun, will be most difficult to reverse.

Meetings like this one are highly important, not only because of the substance of what is reported here, but also because of the evidence and symbolism provided in terms of the renewal and guarantee of the availability of intellectual resources for the future.

In these introductory remarks, I have meant to commend you and endorse your activity. Now I will offer other remarks which concern some issues in the evaluation of research--remarks about how complex, how subtle, and how subjective the evaluation of research is, and about how extremely important an understanding of that complexity is, if the future of health research is to be secure.

In mid-1971 the CIBA Foundation sponsored a "Symposium on Civilization and Science: In Conflict or Collaboration?" H. Bloch, Vice President of the Swiss National Science Foundation, said the following in his introductory remarks:

"In most countries, science budgets have not received the expected increases but have been reduced, rendering the competition for funds fiercer and the need for guidelines for intelligent policy decisions more acute. Also, a world-wide anti-science movement has . . . emerged, which contrasts our technological world with all its

shortcomings and imminent dangers with a romanticized view of the past seen as a bucolic golden age ruined by the advance of science.

"The question of the worthwhileness of scientific activities was almost taboo when it was mentioned at the meeting in 1967." (Dr. Bloch is referring to an earlier CIBA Foundation Symposium on "Decision Making in National Science Policy.") "But now powerful voices from scientific as well as non-scientific quarters are saying that scientists should become more socially responsible, that science should be tolerated and supported only as long as its results are socially relevant, and that science must be constitutionalized and controlled if it is not to destroy our civilization. It is said that the scientist's lack of values has left him helpless to prevent science from being used for exploitation and destruction. And in the minds of many, science, all the way from nuclear physics and engineering to biology and medicine, has become a most dangerous evil."

In a thoughtful and scholarly discussion on "The Limitations of Modern Medicine," John Powles raises a related but somewhat different issue. His own abstract of his paper is as follows:

"The contrast between the enthusiasm for current developments within medicine and the reality of decreasing returns to health for increasing effort is taken as a starting point for an enquiry into the wider medical culture of industrialized societies. It is suggested that a large and increasing proportion of the contemporary disease burden is man-made and that the 'engineering' strategy (of physical and chemical intervention in sick persons) which now dominates the technical side of medicine is not making much progress. Its

momentum can only be fully explained by arguing that medical technology is also serving non-technical purposes.

"It is argued that the problem of diminishing returns within medicine is a specific instance of the wider crisis in industrial man's relationship to his environment. Resource shortages and other pressures are likely to push medicine toward the alternative--'ecological'--strategy for the further improvement of health. The 'demystification' of high medical technology will enable the emotional and existential aspects of illness to be given more direct recognition."

I will quote a little bit further from this thought-provoking article because some of Powles' remarks also relate to the matter alluded to earlier--namely, the positive attractions which I believe are appropriately drawing some good and thoughtful people away from careers in academic biomedical research.

"The engineering approach to the improvement of health has been dominant over an alternative approach which would emphasize the importance of way-of-life factors in disease--an approach which could be described as 'ecological.' While it is to changes with which this latter approach is concerned that industrial man largely owes his current standard of health, it is in the engineering approach that he has placed his faith. Curative medicine has not been very successful in reducing the impact of diseases of maladaptation. Against heart disease there has been almost no real progress. Surgery has secured some modest gains against cancer, but the overall burden has not been significantly reduced. While it may be argued that the current strategy still offers the most hope--especially as significant changes in the

pattern of life seem unlikely--the nature of the underlying disease processes involved make improbable that curative interventions will be very successful. Lord Zuckerman recently reported to the Prime Minister of the U.K. that there was 'likely to be diminishing returns in terms of additional lives saved from increasing expenditure on (cancer) research.' Nor can there be any guarantee that industrial populations have already exhausted the possibilities in respect of diseases of maladaptation. If technological 'advances' continue to be pursued and implemented with little regard for the impact on man's biology, there may well be an additional twenty-first century equivalent of the current epidemic of ischaemic heart disease. Medical technology may have to run fast just to compensate for increased insults to the human organism.

"It is therefore concluded that the problem of diminishing returns is a real one. It results from the nature of the contemporary disease burden and the limited front on which medical effort has been concentrated."

Powles' argument and discussion represent a carefully documented challenge of the sort which is heard from the various custodians of public funds at the national level both in the Administration and to some extent within the Congress. These policy makers want to know prospectively just what will be purchased by continued or increased allocation of money to biomedical research. Retrospective arguments of the kind which many have presented regarding real economic savings as well as reduction in human misery by discoveries such as the polio vaccine seem currently to have little impact in the face of the questions

regarding marginal return on increased future investments. The question almost sounds as if it were put this way:

"We gave you two billion dollars last year, what did you do with it? or, "Suppose next year you get x million dollars more or less than last year, what difference will it make in actual outcomes?"

Depending upon the questioner, the inquiry might be: "What will be the return on new dollars invested, in terms of lives or dollars saved?" Alternatively: "Show us your plan describing how many dollars should be invested in basic research, in applied, in what disciplines, or what categories of disease." No doubt, from the viewpoint of the nonscientist, these questions seem sensible and responsible. The non-scientist policy maker or budget reviewer regards the provision of answers as part of what is called proper accountability.

The demand for accountability in the expenditure of public resources is one which I enthusiastically support. Along with other consumers I strongly agree that it be made an obligation of any individual or organization providing goods or services to the public. However, just what does accountability mean in terms of public programs, and how will we know unequivocally when it has been achieved? The best general discussion of this matter which I have read is one provided by Dr. Alice Rivlin, an economist recently appointed director of the Congressional Budget Office. Dr. Rivlin has been especially concerned with social benefit programs of the Department of Health, Education, and Welfare. She argues that social programs, initiated as the result of a myriad of partially conflicting influences from public interest,

self-interest groups, the Congress, and the Executive Branch, usually have, at best, ill-defined goals. With the diffuse nature of the goals, there is also a consistent failure to stipulate objectives which are to be accomplished in the approach to those goals. Hence, at the time of reckoning, when accountability is to be provided, consensus is lacking on criteria by which to judge whether or not funds have been spent for the purposes intended.

This interpretation of the meaning of the word "accountability" is close to one of the meanings of "evaluation," which sometimes simply means to judge whether one's efforts to accomplish a particular task have been successful or not. Alternatively, evaluation might be highly subjective and individualistic, but under those circumstances, of course, also quite disputable. A similar absence of objectives, if not goals, for biomedical research is part of the cause for current dissatisfaction with its accomplishments. Of course, the reasons for the lack of identifiable objectives for biomedical research are somewhat different from those for social programs in general, and we will examine that shortly.

Unfortunately, the absence of generally agreed upon objectives for biomedical research, or the failure to display plans for the expenditure of resources and to describe the effect of marginal dollar investments, is regarded by some as evidence of a difference in values between the two cultures, science and non-science. Worse still, the non-response can be interpreted as mere intransigence. I believe that the issue of value differences between these two cultures has been grossly exaggerated with respect to the contemporary scientist and the society

in which he finds himself. The explanation of the misunderstanding lies rather more with regard to the selection of proper strategy for the successful accomplishment of research than with values or goal differences. Scientists are no less interested than other members of society in doing social good or in seeing humanity benefited through their efforts.

However, there is a further source of confusion. It is also true that scientists in judging other scientists--that is, in evaluating the work of colleagues--have for some important reasons been inconsistent or in dispute with one another regarding those qualities of research on which one should place the highest values. Certainly, elegance of experimental design, the degree to which true creativity appears to be manifest, and even for some few, the extent to which the research is abstruse or removed from practical purposes are significant values. Perhaps most commonly, a high regard is placed on the extent to which a piece of work provides new insight into the internal logic of the particular science. Investigators whose work shows such characteristics continue to receive support from peer review, and are the recipient of academic promotions and other sorts of status or prestige reward regardless of the value placed on their findings by non-scientists.

The undeniable existence of this value scale leads some non-scientists to charge, as has recently been the case in statements published both in the lay press and in some quasi-professional or para-science journals, that scientists have their heads in the clouds. Aside from the fact that the most lofty and unfettered thinking is exactly what some scientists should be indulging in, there has been a pretty clear intimation that

biomedical scientists, if not actually socially irresponsible, have been insensitive to society's problems. The tenor of the comments is such as to give one the picture of scientists oblivious to the miseries of the real world and to the economic facts of life frittering away time and resources in the indulgence of whimsical and chimerical hobbies. No doubt, this states the position rather more bluntly than its proponents would want to take ownership for, but I assure you that the sentiment is real.

Partially the pressure arises from the fact that through higher level decisions within the Administration and the Congress, the amount of money which will be made available for health research is set at some level less than that needed for the continuation of all that is now ongoing plus all that it would be desirable to do. Health leadership, seeing immediate problems in the apparent overuse or inappropriate use of national resources for health care, would prefer to divert some of the dollars currently available for traditional biomedical research into the study of applied problems, the solution of which offers immediate prospects for the reduction of health care cost. Thus some of what seems a value difference is accounted for by having different time horizons for obtaining results. Scrupulous examination of current health care practices, not alone in order to reduce costs but more importantly to improve the quality of care, is indeed a laudable goal. Whether or not this goal should take precedence over, or be accomplished through reallocation of dollars away from, biomedical research--or whether short-run needs should displace long-run--is an entirely different matter worthy of vigorous public debate.

Preferably one ought to demand resources adequate for both purposes.

The position of those who defend the prevailing level of biomedical research is politically weakened by an inability to place a predicted value on much of the outcome. The best that seems to be generated is a defense which says that the portion of biomedical research which does not find current application represents an investment to be cashed sometime in the future. As I have noted previously, scientists are not necessarily in agreement on the current criteria by which research accomplishments ought to be evaluated, let alone willing to make definitive projections of future value. Valiant attempts have been made to use such measures as numbers of papers published, the number of times work is cited, awards won, and the like to evaluate the output of individuals, institutions, or programs, but all have serious deficiencies even for interim purposes.

Now I would like to talk further about the etiologically related difficulties in evaluating research results, and about practical limitations in the planning or targeting of research. Although hazards in this respect are reasonably well understood within the research community, it would seem that explanations offered have been unconvincing to many non-scientists. In fact, one of the important purposes of my talk today is to remind you of this whole area of mal-communication and to describe to you some careful efforts which have been made in an attempt to explain and document the uncertain, meandering course of scientific discovery. In addition, the studies which I will describe have had, as a secondary purpose, an intent to discover clues about the scientific

discovery process itself in order that support mechanisms might be consciously selected.

These studies which I will discuss briefly are, first, TRACES or Technology in Retrospect and Critical Events in Science and a subsequent study which extended the former and was titled simply, Science, Technology, and Innovation. Both were done for the National Science Foundation. I will show a few slides illustrative of selected portions of the two studies. TRACES , which was reported in December 1968, consisted of a series of retrospective analyses in which were identified the significant turning-point events in the evolution of a number of technological innovations which have had high social impact. The second study reexamined several of the case histories first developed in TRACES and added some additional ones. The methodology in the later study was improved. I will not review these studies in extenso, but only look at three case histories of special relevance for medicine. This brief review will therefore not do justice to the interesting methodology employed, nor discuss a number of the implications of the findings. I intend to illustrate, in a general way, the tortuous and unforeseeable course of biomedical research and to illustrate why there is often a long delay before basic discoveries come to fruition in application. Attempts to evaluate the basic discoveries at a time shortly after they are made are of little enduring value. They also tell hardly anything about when the research will find direct application. Furthermore, most attempts to plan or schedule systematically and in detail an eventual innovation would also appear futile.

Incidently, I am not talking about the process called serendipity. Although many here will be familiar with the term, and although it is a bit of a digression, it seems worthwhile to spend a moment on this. I believe that we have in fact done a disservice to scientific discovery in promoting the freedom of science as being necessary in order to permit serendipity. For those who might not know--the term was derived from Walpole's tale of the three princes of Serendip who in their travels were always discovering, by chance or sagacity, things they did not seek. The word has now come to mean, the gift of finding valuable or agreeable things not sought for. Because of so much talk about this phenomenon, which really does have some limited importance, many non-scientists seem to believe that much of scientific discovery is hit-and-miss. They think that basic research is done in the hope of making chance discoveries somewhat as in throwing dice or playing roulette. Some of the skepticism regarding the support of basic research reflects the misunderstanding that its supposed inefficiency and a substantial part of the cost are attributable to chance tosses which did not make a lucky strike.

Instead, what we should emphasize in speaking of the need for autonomy and freedom in science is that scientific discovery is primarily a result of the fortunate linking of creativity and dogged persistence. A useful description of the creative process is given by E. P. Torrance:

"Creative behavior occurs in the process of becoming sensitive to or aware of problems, deficiencies, gaps in knowledge, missing elements, disharmonies, and so on; bringing together in new

relationships available information; defining the difficulty or identifing the missing element; searching for solutions; making guesses, or formulating hypotheses about the problems or deficiences; testing and re-testing themselves; perfecting them; and finally communicating the results." (The reference is "Creativity" by E. Paul Torrance, Fearon Publishers, Belmont, California, 1969). It is this complex, fragile process for which there must be freedom. It is worth noting that in the TRACES study, by actual count, employing a defined typology of some 21 varieties of decisive events rated moderately or highly important in each innovation, serendipity ranked eighteenth in frequency of occurence.

Now to return from our digression to the actual case histories. The first of these, taken from the TRACES study, outlines the development of the electron microscope. (First slide.) The complexity of the discovery/innovation process is immediately apparent. Do not be distracted by the myriad of detail and illegibility. The two charts from the second study will be greatly simplified.

Note first of all that an arbitrary beginning time of 1860 has been chosen. Of course, it would be possible to go farther back--for example, into the history of the discovery of electricity-- but that would not add greatly to the illumination of the study. Next note that there is a key in the lower left-hand corner identifying each decisive or significant event as being nonmission research, mission-oriented research, or development and application. The heavy, red, straight lines define generally converging fields of study. What is of great significance is the numerous crossing connections between events in

different fields prior to their ultimate convergence and culmination in the innovative discovery, the electron microscope. Note that simultaneous developments in multiple related fields were required, and that even this depiction does not include developments in such less closely related and necessary fields as high-vacuum technology and materials development. The fields most closely related are cathode-ray tube development, electron optics, electron sources, wave nature of electrons, and wave nature of light.

The few additional points which I wish to make concerning these historical case studies are better seen in simplified charts from the second of the National Science Foundation's sponsored investigations. The first history is that of the cardiac pacemaker. (Slide 2.) This history begins at 1900, although, as the study points out, precursor events occurred well before the twentieth century. Electrical stimulation of muscle was first observed by Galvani in 1790. How could Galvani's contemporaries have looked ahead almost 200 years to foresee the value of that discovery? Electrical stimulation of the heart was proposed in 1862, but it was about a century more before the first pacemaker was implanted in a human being. The idea of periodic electrical stimulation of the heart was propounded in 1928 by A. S. Hyman, as indicated by the blue hexagon. The maturation of his idea required among other events the invention of the transistor and advances in miniaturization and pulse circuitry. These evolved from technology developed during World War II, as did other necessary components such as the zinc-mercuric oxide alkaline cell. Later requirements

included epoxy for potting the electronic components and the development of biocompatible silicone encapsulation material for long-term implantation. Parallel advances in heart surgery were of course essential. The TRACES study also discussed the need for evolving moral, religious, and social attitudes in the acceptance of innovation.

The third study certainly necessitated such changing social values, although we will look mostly at the biomedical and technological aspects. (Slide 3.) This chart traces the development of oral contraceptives. In this instance, the time span extends over 40 years. The case history shows that the earliest suggestion for an oral contraceptive was made by Haberlandt in 1921. His proposal was made on the basis of what some might have seen as an experiment with little potential for application to human health--namely, the transplantation of the ovaries of pregnant rats into non-pregnant ones. The effect was to induce temporary sterility in the recipient animals, characteristic of the pregnant animal. On this basis Haberlandt speculated that a substance was produced in the ovaries during pregnancy which might have application as a contraceptive. Evolution of this idea into an innovation affecting human health did not actually come to fruition until the marketing of Enovid in 1960.

If a President and Congress aroused by the threat of population increase and food and energy shortages had mandated a targeted, massively funded program when Haberlandt first made his suggestion, would the time required for application of the idea of oral contraceptives have been shortened? Furthermore, without in any way meaning to diminish the importance of oral contraceptives in permitting family

planning at a unit level, clearly world-wide population control will depend upon the resolution of a great many additional related problems. Does not the development of oral contraceptives represent only a partial--a necessary but not sufficient--piece of the total solution? This is a nice instance of an engineered but insufficient solution to a human health problem of the sort which Powles discussed. When the protagonists of increased funding for biomedical research, and the science administrators responsible for allocation of resources among fields, consider the potential marginal value of additional dollars invested in the basic study of female reproductive physiology versus the study and influence of socioeconomic factors in population control, how do we answer the question as to where the dollars will be most effectively spent both for the short run and for the long? The dilemma is that the social imperative for responsibility and accountability press for a clear answer. However, the complexity and unpredictability of biological research, let alone the unforeseeability of culture and mores altering events in the socioeconomic realm, are likely to lead the scientist administrator to attempt to evade an explicit answer to the question. He will prefer to hedge his bets, and to maintain a highly dynamic stance permitting resources to flow dynamically at almost a microlevel--for example, at the project- and center-grant level--so that progress is made most opportunistically across an extremely broad front of ignorance.

Now we may return to the example of the evolution of the oral contraceptives where we left it temporarily. The conversion of Haberlandt's suggestion into practical application required at least

the following discoveries and events, some of which certainly did not have as a main target the control of human conception. Basic studies in reproductive physiology were required to tease out and identify the various hormones and their roles in ovulation. As early as the mid 1930's Kurzrok identified the ovulation-inhibiting hormone, but no orally active progestin was available. Simultaneously, work of no direct relationship was occurring in other laboratories elucidating structure and synthetic mechanisms for a wide range of steroids. By 1940 R. E. Marker had discovered that diosgenin, a botanical raw material, could be utilized as the basis for steroid synthesis. Marker knew of the isolation of diosgenin from the root of a native yam by Japanese investigators and visualized a commercial effort that would not be dependent upon the availability of animal organs. After an extensive search in the United States and Mexico, involving more than 400 species of botanicals, Marker found his source in a Mexican yam which required no explicit cultivation. In 1944 Marker organized the Syntex Company to produce steroids from diosgenin. Spurred by a large-scale market for steroids in the early 1950's, based largely on the independant discovery of clinical applications for cortisone, production rose from laboratory to industrial levels. Research was also stimulated in more wide-ranging studies of steroid synthesis and structural modifications. Progesterone and related compounds were naturally enough included in this multi-laboratory based effort, which was coordinated only through the usual mechanisms of scientific information exchange--the invisible colleges, general and invitational meetings, and publication in scientific journals.

The remainder of the story is equally fascinating and illuminating, but I will skip over it briefly in the interest of conserving time. For the usual complex human motives, no doubt relating both to Malthusian beliefs and to the achievement of autonomy and equal status for women, Margaret Sanger of the Planned Parenthood Federation, and the philanthropist Mrs. Stanley McCormick, in 1951, requested a proposal from Dr. Gregory Pincus of the Worcester Foundation for Experimental Biology involving a program on contraceptive methods. By that time, the spontaneously converging discoveries concerning the control of the menstrual cycle in the human female, and the other events which I have mentioned, were at a point that Dr. Pincus could propose development, testing, and demonstration of a contraceptive pill. Both Syntex and G.D. Searle Company had produced the steroid analogs norethisterone and norethynodrel, which had high progestational activity when taken orally. Furthermore, societal attitudes were then appropriate for a sufficiently large investigative and demonstration effort which, despite some opposition, was established in Puerto Rico.

Where conception control will go next through hormonal manipulation is not at all clear. Many factors, not the least of which is criticism of male-dominated research by women's rights groups, are pointing in the direction of analogous efforts addressed to control of spermatogenesis. The technical problem at the moment is that effective agents also interfere with potency, which seems somehow to moderate consumer acceptance.

Among those who have written most analytically and incisively about the problems of high-level allocation of resources within science

is Dr. Alvin Weinberg, former director of the Oak Ridge National Laboratory. I'd like to review briefly two of Dr. Weinberg's ideas in order to make you familiar with them in concluding this talk. Weinberg has particularly championed the concept of dividing the problems in which science must interact with society into several categories. He would have us think of problems which are purely scientific, those which are purely political, and others which he characterizes as trans-scientific. The trans-science problems are those which can be asked in scientific terms but which for one reason or another cannot be answered by science given its present state of knowledge.

I am greatly simplifying this discussion, which has many ramifications; and of course, the separation of classes of problems is by no means always clear-cut, nor will there be general agreement about the classification of particular problems. Nevertheless, the concept is useful because it forces us to think critically about the difficulty in separating what, on first examination, appears to be a purely scientific matter from issues which indeed involve general concern and therefore, in a democratic society, fall into the realm of political issues. Weinberg and others who have addressed these matters in a scholarly fashion repeatedly emphasize the need for dynamic interaction accompanied by mutual respect in the resolution of the problems of the sort we have discussed here earlier--namely, the planning of research and the application of resources in accordance with planning efforts.

The second general area to which Weinberg has contributed recently by an excellent analysis has to do with questions of grand strategy. In this instance, Dr. Weinberg has discussed and sorted general science problems into two large categories. The essential basis for categorization is the clarity with which the goals and objectives of the program can be set. If goals and objectives can be set clearly, then the program can be highly targeted and receive central direction. On the other hand, as in much of biomedical research (but not, incidentally, health care research), goals can be fairly well stipulated but objectives are extremely difficult to define. Under the latter circumstances, Weinberg pleads for increased utilization of institutional strategies as opposed to centrally directed strategies. He advocates the support of very large laboratories with general purpose missions, similar to the national laboratories of the Energy Research and Development Administration (formerly AEC). The National Institutes of Health is also an institution of this sort.

Biomedical research has evolved a somewhat different strategy which has, in fact, proved to be highly successful and is a world-wide model. For the most part, we employ the institutional approach; however, the institution is multicentric and highly diffuse, extending throughout the entire nation and manifest primarily in academic institutions. It would appear that biomedical research has been handicapped recently by an ill-conceived attempt to infuse into it the thinking and strategizing quite appropriate to some other areas of science and of health service research. Biomedical research falls into the arena where, for the most part, centralized planning at the level of disease categories is simply not a productive strategy. The situation

is complicated by the fact that some general biomedical research problems--as for example, notoriously cancer or artherosclerotic heart disease--are at a stage where some specific aspects close to an application level are actually indeed susceptible to an overall targeting strategy. We are confronted with a tendency to generalize from such specific instances into the entire realm of biomedical research without regard to the different stages of evolution of the many problems.

In this discourse the two large areas with which I have been concerned are the quite closely related topics of resource allocation and planning, and the matter of accountability in the expenditure of funds for biomedical research. I have tried to suggest the extent to which values within and outside of science determine what research is done and the basis for supposed existence of a gap between science and society in basic values. I have agreed with the general notion that there are indeed values within science which are related to the reward system within the science community and that these values are not shared by society generally. I have also presented the proposition that the existence of these value differences--the historical and cultural sources of which would be of great interest to discuss--are in fact not a fundamental source of conflict between science and society in respect to the politicized issues of planning and accountability. Instead, differences in this regard represent differing perceptions of the most effective strategy and tactics which can be employed in biomedical research. I would further suggest that the overall decisions regarding

resource allocation or gross levels of funding are, in the last analysis, political decisions based on the ways in which society prefers to place its effort. On these questions, science can dispassionately but not conclusively suggest areas which are worth pursuing, either for the development of the internal logic of science or for the possibility of immediate application, and can give some general judgments regarding the likelihood of favorable outcome. On the other hand, with respect to the matters of strategy and tactics to be pursued within biomedical research, nonscientists ought to be highly attentive to the views of scientists who are actually working the problems.

It is indeed true that in this country, and in other democratic, developed countries, the public is increasingly insistent upon being dealt into the decisions involving issues in science that had formerly fallen solely within the purview of the scientist. This is a part of a general change in the way western society makes decisions which has been occurring over the past 200 years at least. In sociological terms this represents a change from vertical decision-making to one far more horizontal. The consequence of this change is that the scientist must either choose to resist and thus risk further loss of public support, or he must welcome the public and invest a substantial amount of time and patience in public education, particularly with respect to the impossibility of answering some apparently sensible and rational questions.

My personal conclusion is that the evolutionary development of biomedical research in the United States has led to an entirely healthy arrangement which is appropriately sensitive to society's

needs and, by reason of the wisdom built into the system involving participation by both scientists and nonscientists in very large numbers, has produced a dynamic and flexible support system. This system has permitted mechanisms which allow for a high measure of targeting and planning in instances when biomedical research is close to an application stage and can be fostered most effectively in this fashion. It has also permitted the development of very large institutional bases for broad-scale studies within general areas of medicine, such as research institutions and centers. These permit a conjoint attack in areas where basic science development is progressing alongside testing and refinement of knowledge close to an application stage. In a very large amount of research, the coordination occurs entirely through means that we are all familiar with--namely, scientific journals and other informal communication. Some problems at the application level, such as large-scale clinical trials, are appropriately managed by central direction. Progress is possible across an extremely broad front of ignorance whenever a salient can be developed and one or a few individuals see an opportunity to exploit it for the advance of knowledge.

Highly targeted efforts are appropriate in some branches of science at some stages in their evolution. They are also appropriate for some activities within the area of biomedical research. However, to extrapolate from the success of such efforts directly into the proponderent areas of ignorance in biomedcine is likely to represent an error in strategy which, instead of leading to the earlier application of knowledge, might in fact destroy the momentum

of advance on a broad front. Judicious discrimination free of demagogic influence is required for the distribution of limited resources.

This talk has been intended to bring to your attention some matters concerned with the garnering of support, in both opinion and dollars, and with the administration of biomedical science. If it has stimulated you to further thinking about these, it will have been a useful expenditure of time. Walter Rosenblith has recently expounded the idea that every scientist and scientist administrator owes a tithe on his time to the promotion of society's understanding of science. I strongly subscribe to that notion and am seeking to make whatever contribution I can in this direction. My hope is that you, too, will accept this obligation and continuously hold yourself prepared to discharge it effectively. I do wish you all continued success, and expect that your interest and involvement will ensure the continued good health of biomedical research in this country.

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